

November 2015

Tardive Dyskinesia: Reducing Medical Malpractice Exposure Through a Risk-Benefit Analysis

John Baker

Follow this and additional works at: <https://via.library.depaul.edu/jhcl>

Recommended Citation

John Baker, *Tardive Dyskinesia: Reducing Medical Malpractice Exposure Through a Risk-Benefit Analysis*, 1 DePaul J. Health Care L. 799 (1997)

Available at: <https://via.library.depaul.edu/jhcl/vol1/iss4/6>

This Article is brought to you for free and open access by the College of Law at Via Sapientiae. It has been accepted for inclusion in DePaul Journal of Health Care Law by an authorized editor of Via Sapientiae. For more information, please contact digitalservices@depaul.edu.

TARDIVE DYSKINESIA: REDUCING MEDICAL MALPRACTICE EXPOSURE THROUGH A RISK-BENEFIT ANALYSIS

*John Baker**

INTRODUCTION

An academic physician once postulated a truism accepted by most clinicians, but often disregarded by both the lay and legal communities: "Few drugs that help anybody will not hurt somebody, and all potent drugs, no matter how skillfully used, can cause untoward effects in some patients."¹ Antipsychotic drugs are extremely helpful in pharmacotherapy and have, likewise, revolutionized the treatment of schizophrenia.² Antipsychotic drugs are also effective in treating "paranoid and schizophreniform disorders, brief reactive psychoses, schizoaffective disorders, atypical psychoses, manic episodes, major depressive disorders with psychotic features, certain organic psychoses, and some borderline patients."³ Further, these drugs are credited with substantially decreasing the number of mentally ill hospital patients.⁴

An estimated three million Americans were prescribed antipsychotic drugs in 1986, and 945,000 new patients are prescribed antipsychotic drugs each year.⁵ The only efficacious drug treatment for schizophrenia

*Fgfgfg. B.A., Notre Dame, 1988; J.D., Notre Dame, 1993; LL.M. in Health Law, DePaul University, 1997.

¹Smith & Simon, *Tardive Dyskinesia Revisited: A Major Health Crisis*, 31 MEDICAL TRIAL TECHNIQUE QUARTERLY 342 (1985), quoted in Koch-Weser, *Fatal Reactions to Drug Therapy*, 292 NEW ENG. J. MED. 302-303 (1974).

²See H. KAPLAN, SYNOPSIS OF PSYCHIATRY 1111 (1994).

³Davis et al., *Clinical and Legal Issues in Neuroleptic Use*, 6 CLINICAL NEUROPHARMACOLOGY 117, 118 (1983).

⁴Smith & Simon, *supra* note 1, at 344.

⁵C. Thomas Gualtieri, M.D. et al., *Tardive Dyskinesia Litigation and the Dilemmas of Neuroleptic Treatment*, 14 J. PSYCHIATRY & LAW 187, 204 (1986).

is antipsychotic drugs.⁶ Significantly, these drugs enable millions of people to lead healthy and more productive lives, however, not without costly side effects⁷ that may include: acute dystonic reactions, Parkinsonian Syndrome, akathisia, akinesia, Rabbit Syndrome, and Neuroleptic Malignant Syndrome.⁸

One of the more serious side effects of antipsychotic drugs is Tardive Dyskinesia (TD).⁹ TD is a disorder characterized by involuntary movements of the face, trunk, or extremities, and is often associated with the prolonged exposure to dopamine receptor drugs such as antipsychotic drugs.¹⁰ Involuntary movements include: frowning, blinking, grimacing, puckering, chewing, smacking, rolling of the tongue, foot tapping, and rocking of the hips.¹¹ Other drugs, such as the antidepressant amoxapine, and the antiemetic agents metoclopramide and prochlorperazine, are also known to cause TD.¹²

The term "tardive" refers to the fact that the condition usually develops only after a prolonged antipsychotic drug regimen of at least six months, whereas "dyskinesia" refers to the involuntary movements resulting from the actual drug use.¹³ "Neuroleptics" is another name for antipsychotic medications, and the name itself suggests these drugs may produce undesirable side effects on the central nervous system.¹⁴ It is

⁶See Brakel & Davis, *Taking Harms Seriously: Involuntary Mental Patients and the Right to Refuse Treatment*, 25 IND. L. REV. 429, 449 (1991).

⁷See TEXTBOOK OF PSYCHIATRY 905 (A. Hayes & S. Yudofsky eds., 1994) [hereinafter HAYES & YUDOFSKY].

⁸*Id.* at 909. Acute dystonic reactions include bizarre and sustained postures of the face, jaw, tongue, neck, and trunk. These reactions can occur within days after starting medication and can disappear when the drugs are discontinued. Akathisia can be defined as motor restlessness which is relieved by moving. It also gradually disappears when the drugs are discontinued. Drug-induced Parkinsonism causes patients to exhibit the tremors and rigidity of those afflicted with Parkinson's disease, but can also be treated effectively with drugs. Akinesia is defined as a behavioral state of diminished spontaneity characterized by few gestures, unsponaneous speech, and apathy. Rabbit syndrome consists of rapid movements of the lips that mimic those of a rabbit. This syndrome, too, can be easily treated. Neuroleptic malignant syndrome is a rare but potentially fatal disorder characterized by mental status changes, rigidity, delirium, severe anxiety, mutism, elevated white blood cell count, tachycardia, and diaphoresis. *Id.*

⁹*Id.*

¹⁰*Id.* at 912.

¹¹*Id.*

¹²*Id.*

¹³See 2 COMPREHENSIVE TEXTBOOK OF PSYCHIATRY 2005 (H. KAPLAN & B. SADOCK, 6th ed. 1995) [hereinafter KAPLAN & SADOCK].

¹⁴*Id.*

relatively rare that TD's effects are considered disabling, since few people suffering from this disease experience difficulty walking, breathing, eating, or talking.¹⁵ Nevertheless, because 10 to 20 percent of those patients treated with antipsychotic drugs for more than one year experience TD, the administration of these drugs has recently stirred much controversy and subsequent litigation affecting the psychiatric field.¹⁶

Although advocates in the medical and legal communities recognize the risks of antipsychotic drug use, many lose sight of the benefits associated with these drugs, a fact that often frustrates the medical community.¹⁷ Notably, antipsychotic drugs allow millions of people to return to work or school, and often mean the difference between institutionalization and community living for the patient.¹⁸ In the event a patient discontinues antipsychotic drug treatment, relapse is often inevitable, painful, and costly.¹⁹ In addition, the deteriorating effects of discontinuation are potentially irreversible.²⁰ Consequently, the repercussions associated with either relapse or untreated schizophrenia affect the patient, family members, mental institutions, and society in general.²¹

While the benefits of antipsychotic drug use are evident and quite profound, the risks, though often overstated, are real.²² Antipsychotic medication, for example, is similarly used to treat neurotic anxieties and/or character disorders for which efficacy is yet to be established.²³

¹⁵HAYES & YUDOSKY, *supra* note 7, at 906.

¹⁶R. SIMON, *CLINICAL PSYCHIATRY AND THE LAW* 211, 231 (2d ed. 1992).

¹⁷See Brakel & Davis, *supra* note 6, at 441.

¹⁸APA Report Summarizes Recent Developments in Prevention and Treatment of Tardive Dyskinesia, 43 HOSP. COMMUNITY PSYCHIATRY 413 (1992) [hereinafter *APA Report*].

¹⁹*Id.*

²⁰See Brakel & Davis, *supra* note 6, at 457.

²¹*Id.* The reader should note that nearly thirty percent (\$19 billion) of schizophrenia's cost involves direct treatment and the rest is absorbed by other factors — lost time from work for patients and care givers, social services and criminal justice resources. Schizophrenia affects one percent of the population but accounts for a forth of all mental health costs and takes up one third of the psychiatric beds. Since most schizophrenic patients are never able to work, they must be supported for life by Medicaid and other forms of public assistance. The debilitating nature of the illness brings enormous family and societal costs that often go unnoticed because they are not reported to health insurers or mental health agencies. *Id.*

²²See Smith & Simon, *supra* note 1, at 344.

²³*Id.* The consensus of opinion in the literature asserts that antipsychotics should virtually never be used with conditions such as character disorder or anxiety. The risk of TD is much higher with such use and alternative treatments are much more successful. If the physician uses antipsychotics for such conditions, he should carefully document his reasons. *Id.*

Thus, when treating schizophrenic patients, the psychiatrist must assume responsibility for both the risks and the benefits of antipsychotic medication.²⁴

This article discusses the risks and implications of antipsychotic drug use, and the nexus between these drugs and TD. Having already discussed the primary concerns involved with antipsychotic drug use in Part I of this article, Part II establishes the requisite medical foundation upon which antipsychotic drug use and TD exist. Combined with this medical background, Part II explores TD risk factors, assessment techniques, and drug treatment variables and strategies. Part III attempts to provide insight into preventing TD malpractice claims. Specifically, Part III focuses on clinician liability and the appropriate standard of care for patients taking antipsychotic medication. Part IV analyzes various jury verdicts and settlement agreements from TD malpractice claims nationwide. Part V discusses the doctrine of informed consent and in particular, seeks to define the requisite disclosure and patient consent necessary for antipsychotic drug treatment. Part VI addresses the controversial debate surrounding a patient's right to refuse treatment by discussing three different approaches, the "rights-driven" approach, the "treatment-driven" approach, and independent clinical review, and this part of the article further considers how each of these approaches uniquely impacts the right to refuse treatment debate.

The ultimate goal of this article is to demonstrate that a careful, well-reasoned, and fully-informed risk-benefit analysis of TD can mitigate tension amongst the medical, legal, and lay communities, thereby improving the standard of patient care and reducing TD malpractice claims. Also, the implementation of a risk-benefit analysis in the administration of antipsychotic medication protects the clinician from the undesirable consequences of judicial "judgment by hindsight," and leads to consistent and factually supported judicial decisions that can be shared, justified, and taught to everyone.²⁵

²⁴See *APA Report*, *supra* note 18, at 413.

²⁵T. GUTHEIL ET AL., *DECISION MAKING IN PSYCHIATRY AND THE LAW* 58 (1991) [hereinafter GUTHEIL]. This author seeks to address the needs and concerns of the medical, legal, and lay communities, and aspires to forge a common ground between them.

MEDICAL BACKGROUND

In order to analyze the relationship between a clinician's decision to administer antipsychotic drugs and the subsequent risk of developing TD, the clinician must identify and examine a variety of factors which include:

- (1) drug treatment variables;
- (2) risk factors;
- (3) methods and variables of assessment;
- (4) methods of prevention; and
- (5) advances in the treatment of TD.²⁶

Since 1973, the Food and Drug Administration (FDA) has warned the medical community of the causal connection between antipsychotic drug use and TD; yet, the psychiatric community still under-recognizes this disease.²⁷ Increased knowledge and understanding of the risk factors, treatment, and even prevention of TD, will likely diminish the seriousness and number of neuroleptic-induced TD cases.²⁸

General Background

The first reported case involving antipsychotic drug-induced TD occurred in 1957, five years after the introduction of antipsychotic drugs.²⁹ Following years of controversy and denial by the psychiatric community, there is currently general agreement that antipsychotic drugs are a major factor in the development of TD.³⁰ However, not all involuntary movements demonstrated by patients who take antipsychotic drugs establish the presence of TD.³¹ In fact, spontaneous tick-like and

²⁶See Latimer, *Tardive Dyskinesia: A Review*, 40 CAN. J. PSYCHIATRY 49 (Supp. 1995).

²⁷See Hansen et al., *Under recognition of Tardive Dyskinesia and Drug-Induced Parkinsonism by Psychiatric Residents*, 14 GEN. HOSP. PSYCHIATRY 340 (1992); Kalachnik & Sprague, *How Well Do Physicians, Pharmacists, and Psychologists Assess Tardive Dyskinesia Movements?*, 28 ANN. PHARMACOTHER. 185 (1994). This under recognition is especially common amongst psychiatric residents. Hansen et al., *Under recognition of Tardive Dyskinesia and Drug-Induced Parkinsonism by Psychiatric Residents*, 14 GEN. HOSP. PSYCHIATRY 340 (1992).

²⁸See Jeste & Caligiuri, *Tardive Dyskinesia*, 19 SCHIZOPHR. BULL. 303 (1993).

²⁹*Id.*

³⁰*Id.*

³¹Several neurologic disorders of the basal ganglia such as Huntington's disease, Wilson's disease, brain neoplasm, Fahr's syndrome, Hallervorden-Spatz disease, and Sydenham's chorea can also produce abnormal involuntary movements. Other identifiable movement disorders include hyperthyroidism, hypoparathyroidism, torsion dystonia, Tourette's syndrome, Meige

perseverative movements often identified with TD have been observed in psychotic patients for many years prior to the introduction of antipsychotic drugs.³²

Spontaneous dyskinesias are poorly understood and difficult to study; yet, they are substantially significant to the clinical and medicolegal fields.³³ An estimated 4 to 7 percent of the elderly population in the United States develop dyskinesia in the absence of antipsychotic drugs, and estimated prevalence rates of spontaneous dyskinesia among schizophrenic patients have reached 30 percent.³⁴ The issue of spontaneous dyskinesia is important to the risk-benefit analysis for prescribing antipsychotic drugs because this factor appears to weaken the causal connection between dyskinesia and antipsychotic drug use.³⁵

The prevalence of TD is difficult to estimate, because incidence rates vary depending on the nature and demographics of the study.³⁶ The American Psychiatric Association (APA) has estimated the prevalence of TD between 15 and 20 percent of patients using antipsychotic drugs.³⁷ Also, the incidence or proportion of any group that is initially free of TD or that will develop symptoms of TD pursuant to antipsychotic drug use within a designated time period is also difficult to estimate.³⁸ Medical studies also indicate that the incidence of TD increases as the length of

syndrome, and spasmodic torticollis. The distinction between tardive dyskinesia and these disorders can be difficult to make, especially for the inexperienced observer. TD is a diagnosis of exclusion and other possibilities should be excluded, especially if the history and medications are unknown. Latimer, *supra* note 26, at 50.

³²APA Report, *supra* note 18, at 413.

³³Latimer, *supra* note 26, at 50.

³⁴*Id.* Data on spontaneous dyskinesia is hard to obtain and it is difficult to determine whether an individual patient's abnormal movements are induced by antipsychotic medication or have developed spontaneously. Therefore, it is likely that tardive dyskinesia's accepted prevalence of 20 percent is inflated because researchers have not adjusted for spontaneous dyskinesia. Age is a definite risk factor for spontaneous dyskinesia. After the age of forty the prevalence of spontaneous dyskinesia is sufficiently high to conclude that many patients with diagnoses of tardive dyskinesia have abnormal movements attributable to causes other than antipsychotics. For an insightful discussion about spontaneous dyskinesia see Khot & Wyatt, *Not All That Moves is Tardive Dyskinesia*, 148 AM. J. PSYCHIATRY 661 (1991); Fenton et al., *Risk Factors for Spontaneous Dyskinesia in Schizophrenia*, 51 ARCH. GEN. PSYCHIATRY 643 (1994).

³⁵Latimer, *supra* note 26, at 50.

³⁶*Id.*

³⁷APA Report, *supra* note 18, at 413.

³⁸Jeste & Caligiuri, *supra* note 28, at 304 (studies of incidence are variable because of the age of patients in the study, their psychiatric diagnosis, and the length of drug treatment).

antipsychotic drug treatment increases.³⁹ In one long-term study where the median length of lifetime exposure to antipsychotic drugs was twelve months, there was a 5 percent incidence level of TD after one year, 10 percent after two years, 15 percent after three years, 19 percent after four years, and 26 percent after six years.⁴⁰

Preliminary studies tracking the course of TD indicated the disorder was progressive and irreversible.⁴¹ Recent studies, however, indicate TD is not progressive in most patients; instead, the individual's condition will actually stabilize, and may even improve.⁴² A number of studies have also documented the course and development of TD among patients who take antipsychotic drugs, and, thereafter, exhibit symptoms of the disease.⁴³ The majority of these studies indicate these patients either demonstrated signs of improvement or showed no significant change in their current condition.⁴⁴ These findings are significant to both the medical and legal fields, and should influence the clinician's decision on whether to continue administering antipsychotic medication to a TD patient.⁴⁵ Clearly, these figures do not support the proposition that a clinician should discontinue antipsychotic medication if TD develops, especially since TD symptoms diminish even with the continued use of medication.⁴⁶ In addition, the risk-benefit analysis is further influenced in the case of severely psychotic patients for whom discontinuing medication would lead to a potentially catastrophic relapse.⁴⁷

³⁹*Id.*

⁴⁰LATIMER, *supra* note 26, at 51.

⁴¹KAPLAN & SADOCK, *supra* note 13, at 2005.

⁴²*Id.*

⁴³*Id.*

⁴⁴*Id.* In a 1994 study done by Gardos & Cole, a group of 122 neuroleptic-treated Hungarian outpatients were assessed for TD over a ten year period. The overall prevalence of TD in this group changed little over time; it was 30.2 percent at baseline, 36.5 percent at five years, and 31.7 percent at ten years. Gardos et al., *Ten-year Outcome of Tardive Dyskinesia*, 151 AM. J. PSYCHIATRY 836 (1994). In another study done in Italy, the course of TD outcomes was followed up for three years in a population of 125 institutionalized patients receiving continuous antipsychotic treatment. The prevalence of TD rose from 39.2 percent at the first examination to 52.8 percent at the last one. However, 28.6 percent of TD affected patients recovered and 30 percent improved. This finding of no certain irreversibility confirms the Gardos study. Cavallaro et al., *Tardive Dyskinesia Outcomes: Clinical and Pharmacologic Correlates of Remission and Persistence*, 8 NEUROPSYCHOPHARMACOLOGY 233 (1993).

⁴⁵See Gardos, *supra* note 44, at 840.

⁴⁶*Id.*

⁴⁷See APA Report, *supra* note 18, at 413.

One study has suggested that rather than viewing TD as "a reversible or irreversible condition, it may be more helpful to view it as being on a continuum from resolution to persistence."⁴⁸ The potentially serious consequences of TD include both physical and psychosocial complications, as well as the inherent complication of persistence.⁴⁹ The most common physical complications of oral dyskinesia include dental and denture problems, muffled speech, and traumatic ulceration.⁵⁰ Swallowing disorders, on the other hand, are not commonly identified with oropharyngeal dyskinesia.⁵¹ Respiratory disturbances accompanied by reflexive grunting, snorting, gasping, and shortness of breath have also been reported,⁵² as have weight loss⁵³ and a shorter life expectancy.⁵⁴ Finally, abnormal involuntary body movements that characterize TD may also produce psychological problems such as depression; because such movements often create a sense of stigma and anxiety for the patient.⁵⁵ Consequently, although TD is potentially disabling, severe forms of TD are rare,⁵⁶ it would be unusual for a clinician to refrain from administering antipsychotic drugs for fear of these uncommon complications.⁵⁷

Risk Factors

Clinical knowledge of the various TD risk factors is critical to determining whether to administer antipsychotic medication. If the clinician provides treatment to a high risk patient, he or she must monitor and guard against burgeoning signs of TD.⁵⁸ Also, the clinician should tailor the patient's drug regimen in an effort to reduce and/or prevent TD.⁵⁹

⁴⁸Jeste & Caligiuri, *supra* note 28, at 309.

⁴⁹*Id.*

⁵⁰*Id.*

⁵¹*Id.*

⁵²*Id.*

⁵³*Id.*

⁵⁴See Mehta et al., *Mortality of Patients with Tardive Dyskinesia*, 135 AM. J. PSYCHIATRY 371 (1978). In this study nineteen dyskinetic patients had died after five years compared with twelve patients in the control group. The results of this research are fairly controversial and other researchers have not found associations between tardive dyskinesia and a shortened longevity. *Id.*

⁵⁵Jeste & Caligiuri, *supra* note 28, at 310.

⁵⁶Gardos & Cole, *Overview: Public Health Issues in Tardive Dyskinesia*, 137 AM. J. PSYCHIATRY 776, 777 (1980).

⁵⁷*Id.*

⁵⁸See APA Report, *supra* note 18, at 414.

⁵⁹*Id.*

The most implicated risk factor for TD, especially the more severe and persistent forms, is increased age.⁶⁰ Many studies indicate there is a strong correlation between a patient's age and the prevalence and severity of TD.⁶¹ Therefore, clinicians must be extremely cautious when administering antipsychotic drugs to elderly patients and any side effects should be carefully monitored.⁶²

A second major set of TD risk factors is age and gender. The prevalence of severe TD among elderly woman is significantly higher than among young women.⁶³ A 1992 review from seventy-six selected studies totaling 39,187 patients, revealed the prevalence of TD was significantly higher among women at 26.6 percent than men at 21.6 percent.⁶⁴ The same survey also evaluated the prevalence of TD among patients from various geographic locations and found TD was less common among patients of Asian descent than patients of North American, European, and African descent.⁶⁵

Clinicians should also warn patients of the following risk factors associated with TD: smoking,⁶⁶ alcohol use,⁶⁷ and the use of antidepressants.⁶⁸ Diabetes mellitus has similarly been identified as a possible risk factor.⁶⁹ Dyskinetic patients also demonstrate indirect evidence of brain damage, such as a perinatal event or traumatic brain injury in infancy or early childhood.⁷⁰

Although TD is primarily associated with schizophrenic patients, patients with primary affective disorders and schizoaffective disorders

⁶⁰*Id.* at 413.

⁶¹Smith & Baldessarini, *Changes in Prevalence, Severity, and Recovery in Tardive Dyskinesia with Age*, 37 ARCH. GEN. PSYCHIATRY 1368 (1980) [hereinafter Smith].

⁶²*Id.*

⁶³APA Report, *supra* note 18, at 413.

⁶⁴Yassa & Jeste, *Gender Differences in Tardive Dyskinesia: A Critical Review of the Literature*, 18 SCHIZOPHR. BULL. 701 (1992).

⁶⁵*Id.*

⁶⁶Jeste & Caligiuri, *supra* note 28, at 305.

⁶⁷Duke et al., *Alcohol Use and its Relationship to Symptoms, Tardive Dyskinesia and Illness Onset*, 164 BR. J. PSYCHIATRY 630 (1994).

⁶⁸Clayton, *Antidepressant-induced Tardive Dyskinesia: Review and Case Report*, 31 PSYCHOPHARMACOL. BULL. 259 (1995).

⁶⁹Woerner et al., *Diabetes and Development of Tardive Dyskinesia*, 150 AM. J. PSYCHIATRY 966 (1993).

⁷⁰Pourcher et al., *Neuroleptic Associated Tardive Dyskinesias in Young People with Psychoses*, 166 BR. J. PSYCHIATRY 768 (1995).

may even be at a higher risk when treated with neuroleptics.⁷¹ Other studies have revealed that mood disorders, including major depression and bipolar disorder, are also risk factors for neuroleptic induced TD.⁷² Nevertheless, in a 1992 report on TD, the APA decried the lack of research directed toward TD risk factors, arguing that such research would aid in the development of TD prevention.⁷³

Assessing Tardive Dyskinesia

A careful and successful diagnosis, coupled with an ongoing clinical assessment of TD symptoms, is crucial toward controlling the development of TD symptoms.⁷⁴ Unfortunately, clinical assessments are often complicated by various methodological problems, and the lack of precise and reliable assessment methods.⁷⁵ For example, voluntary suppression, fluctuation of symptoms due to changes in arousal, posture, mobility or medications, spontaneous increase or decrease of the symptoms of the disorder, and differentiating the diagnosis from other movement disorders all play a role in clinical assessment.⁷⁶ The lack of precise assessment methods may be one of the main factors leading to the inability to adequately delineate the syndrome, determine prevalence, and develop more effective treatment programs to improve these assessment methods that have been utilized over the last fifteen years.⁷⁷

The diagnostic criteria currently employed by clinicians to assess TD include:

- (1) a three month minimum of cumulative neuroleptic exposure;
- (2) moderate abnormal involuntary movements in one or more body areas, or mild movements in two or more body areas; and
- (3) the absence of other conditions that produce involuntary hyperkinetic dyskinesias.⁷⁸

⁷¹*APA Report, supra* note 18, at 413.

⁷²Jeste & Caligiuri, *supra* note 28, at 305.

⁷³*APA Report, supra* note 18, at 413.

⁷⁴Latimer, *supra* note 26, at 49.

⁷⁵*Id.*

⁷⁶*Id.*

⁷⁷Jeste & Caligiuri, *supra* note 28, at 307.

⁷⁸Latimer, *supra* note 26, at 50.

Following a diagnosis of TD, the clinician should initiate a quantitative method of assessment.⁷⁹

The APA has stressed the need for quantitative methods such as multi-item scales to assess TD.⁸⁰ Currently, the most common multi-item scale used to test for TD is the Abnormal Involuntary Movement Scale (AIMS).⁸¹ Other scales include the Rockland Scale, the Extrapyrimal Symptom Rating Scale (ESRS), and the Dyskinesia Identification System Condensed User Scale (DISCUS).⁸² The quality of scoring on rating scales often depends on the experience of the observer,⁸³ and a careful clinician should monitor patients every three to six months to assess for TD.⁸⁴ A 1992 APA Report has also recommended that the clinician, especially one who is inexperienced, consult with a specialist in those cases difficult to assess.⁸⁵

Instrumental assessments for TD first appeared in 1973.⁸⁶ These assessments were designed to enhance clinical understanding of TD, and to distinguish TD from other movement disorders, thereby helping to treat and prevent TD.⁸⁷ In addition, recent advances in computer technology and increased sophistication of instrumental procedures over the past few years have been promising.⁸⁸ Researchers currently use accelerometers, electromyography, force gauges, position transducers, Doppler ultrasound, and digital image processing to detect and differentiate TD from other disorders.⁸⁹

⁷⁹*Id.*

⁸⁰APA Report, *supra* note 18, at 413. The APA has indicated that scores on a rating scale cannot be used to diagnose the patient's condition.

⁸¹Jeste & Caligiuri, *supra* note 28, at 308. The AIMS test identifies seven areas of the body and their most common abnormal movements and assesses each movement on a scale of 0 to 4. The AIMS is a reliable rating for trained observers, but it does not distinguish between TD and other movement disorders. *Id.*

⁸²See Kalachnik & Sprague, *The Dyskinesia Identification System Condensed User Scale (DISCUS): Reliability, Validity, and a Total Score Cut-off for Mentally Ill and Mentally Retarded Populations*, 49 J. CLIN. PSYCHOL. 177 (1993) (The psychometrically derived (DISCUS) cut-off score of 5 or above is a "red flag" that clinicians may use in monitoring individuals prescribed antipsychotic medication).

⁸³Jeste & Caligiuri, *supra* note 28, at 308.

⁸⁴APA Report, *supra* note 18, at 413.

⁸⁵*Id.*

⁸⁶Jeste & Caligiuri, *supra* note 28, at 308.

⁸⁷*Id.*

⁸⁸*Id.*

⁸⁹*Id.* at 308-309. See also Lohr & Caligiuri, *Quantitative Instrumental Measurement of Tardive Dyskinesia: A Review*, 6 NEUROPSYCHOPHARMACOLOGY 231 (1992).

Drug Treatment Variables

The efficacy of antipsychotic drugs to treat and prevent schizophrenia relapse is well established.⁹⁰ Within a twelve-month period, clinical studies have indicated on average 16 percent of neuroleptic patients suffering from schizophrenia relapse, whereas 74 percent of patients who do not receive neuroleptics relapse.⁹¹ However, there is still no consensus on what constitutes an optimal dose of antipsychotic drugs for the individual patient.⁹²

The typical antipsychotic drugs used in treatment include: Thorazine, Haldol, Prolixin, Mellaril, and Stelazine.⁹³ One study has revealed that no one antipsychotic drug is superior, and there is little data identifying specific drugs or drug classes in the development of TD.⁹⁴ Recent data, however, indicates that several atypical antipsychotic drugs result in milder side effects and are equally efficacious in treating psychosis.⁹⁵ The APA has cited, for example, the potential of Clozapine in lowering the risk of TD, but has also determined further research is needed in light of other potential side effects.⁹⁶ A second novel antipsychotic is Risperidone. Although several times less potent than Haldol, Risperidone parallels Haldol in controlling the psychotic symptoms of schizophrenia.⁹⁷

⁹⁰See APA Report, *supra* note 18, at 413.

⁹¹Shriqui, *Neuroleptic Dosing and Neuroleptic Plasma Levels in Schizophrenia: Determining the Optimal Regimen*, 40 CAN. J. PSYCHIATRY 38 (Supp. 1995).

⁹²*Id.*

⁹³There are three major generic classes of antipsychotic agents: phenothiazines (chief brand names are Thorazine, Mellaril, Prolixin and Stelazine); thioxanthenes (chief brand names Taracan and Navane); and butyrophenones (chief brand name Haldol).

⁹⁴Kane & Smith, *Tardive Dyskinesia: Prevalence and Risk Factors, 1959 to 1979*, 39 ARCH. GEN. PSYCHIATRY 473, 476 (1982). The most persuasive argument for prescribing any specific drug is a patient's reaction record to the drug. See HAYES & YUDOSKY, *supra* note 7, at 906.

⁹⁵KAPLAN & SADOCK, *supra* note 13, at 2016.

⁹⁶APA Report, *supra* note 18, at 413. Clozapine's most significant side effects include agranulocytosis, seizures, weight gain, hypotension, and sedation. See Buchanan, *Clozapine: Efficacy and Safety*, 21 SCHIZOPHR. BULL. 579 (1995); Gerlach & Peacock, *Motor and Mental Side Effects of Clozapine*, 55 J. CLIN. PSYCHIATRY 107 (Supp. 1994). Clozapine's other benefits include: effectiveness in 30 to 50 percent of treatment resistant psychotic patients, thus it is the treatment of choice for severely disabling psychotic illness that has not responded to "standard" antipsychotic. See KAPLAN & SADOCK, *supra* note 13, at 2016.

⁹⁷*Id.* at 2017. For an interesting discussion of the potential of risperidone see Keltner, *Risperidone: The Search for a Better Antipsychotic*, 31 PERSPECT. PSYCHIATRIC CARE 30 (1995). The authors maintain the potential for risperidone as a first line antipsychotic because it is arguably better than traditional antipsychotic in treating schizophrenia, but will not likely cause extrapyramidal symptoms and has less severe and fewer side effects than clozapine. See also Marder & Meibach, *Risperidone in the Treatment of Schizophrenia*, 151 AM. J. PSYCHIATRY 823

To date, much research has focused on the design of new drugs to treat psychosis without the possibility of causing dangerous side effects such as TD.⁹⁸ Studies have also been conducted on the optimal antipsychotic drug dosage a clinician should administer, and the various techniques used to administer these drugs.⁹⁹ The results of such research could potentially shift the risk-benefit ratio of antipsychotic drugs from a moderate risk/high benefit to a low risk/high benefit.¹⁰⁰ Because the risk of TD is greater in long-term treatment, acute (short-term) treatment must be distinguished.¹⁰¹ While it is often imperative to administer antipsychotic drugs in an acute situation, it is not always necessary to administer these drugs on a long-term basis.¹⁰²

Medical literature suggests that clinicians should administer the least possible effective dose of antipsychotic drugs to a patient.¹⁰³ Unfortunately, it is often difficult for the clinician to determine the least possible effective dose.¹⁰⁴ Significantly, the authors of a popular medical textbook determined that there are no additional benefits received from the use of high doses, and the greatest medical benefit is reached with "600 to 900 mg a day of Chlorpromazine, which is sufficient for most patients and consistent with an average of 10 mg a day of Haloperidol (Haldol) and upper limits of 12 to 20 mg a day."¹⁰⁵ A higher dose, nevertheless, is often required for a patient who experiences severe psychosis and/or an extremely high degree of agitation.¹⁰⁶ However, the clinician must realize that an antipsychotic drug which causes side effects in one patient may be harmless to another.¹⁰⁷ In fact, a patient may have as much as a twenty-fold variation in blood level after receiving the same antipsychotic dosage.¹⁰⁸ Over one-hundred clinical studies have attempted to delineate the degree of correlation between dose, neuroleptic blood level, and clinical response, but to date these studies have met with only moderate

(1994).

⁹⁸KAPLAN & SADOCK, *supra* note 13, at 2016.

⁹⁹*Id.*

¹⁰⁰*Id.* at 2005.

¹⁰¹Davis et al., *supra* note 3, at 118.

¹⁰²*Id.*

¹⁰³APA Report, *supra* note 18, at 413.

¹⁰⁴See KAPLAN & SADOCK, *supra* note 13, at 2013.

¹⁰⁵*Id.*

¹⁰⁶HAYES & YUDOSKY, *supra* note 7, at 906.

¹⁰⁷*Id.*

¹⁰⁸KAPLAN & SADOCK, *supra* note 13, at 2014.

success.¹⁰⁹ Plasma level determination, however, is useful in recognizing noncompliance and has guided the clinician toward distinguishing between neuroleptic-induced behavioral toxicity and increased psychosis.¹¹⁰

The APA and standard psychiatric textbooks have published various guidelines for initiating antipsychotic drug therapy.¹¹¹ Many psychiatrists are pressured by staff members to control the patient's behavior and, therefore, may increase the dosage or switch antipsychotic drugs prematurely.¹¹² Pursuant to the patient's first psychotic episode, antipsychotic drug treatment should continue for no less than one year.¹¹³ Five years of treatment is recommended once the patient has experienced a second psychotic episode.¹¹⁴

There are several techniques used in antipsychotic drug maintenance therapy. Many research scientists attempt to administer a lower dosage to the patient through intermittent and targeted treatment in order to prevent side effects, such as TD.¹¹⁵ Intermittent treatment involves a fixed administration schedule incorporating medication-free days, whereas targeted treatment limits the use of antipsychotic drugs to periods of incipient relapse.¹¹⁶ The efficacy of intermittent and targeted treatments depends on patient monitoring, which in turn requires an ongoing and well-established therapeutic relationship.¹¹⁷

The APA task force on TD has determined that both intermittent and targeted treatment are not viable forms of treatment for most patient subgroups due to the threat of relapse.¹¹⁸ A common strategy, according to the APA, is continuous low dosage of oral antipsychotic, 2.5 mg per day for oral haloperidol or fluphenazine, or depot dosage, 50 mg to 60 mg every four weeks for haloperidol decanoate, or 6.5 to 12.5 mg every two weeks for fluphenazine decanoate.¹¹⁹

¹⁰⁹Shriqui, *supra* note 91, at 39.

¹¹⁰*Id.* Note that it is often difficult to determine plasma level concentrations for the average clinician (as opposed to research scientists) because of cost and time constraints. *Id.*

¹¹¹See HAYES & YUDOSKY, *supra* note 7, at 907.

¹¹²KAPLAN & SADOCK, *supra* note 13, at 2014.

¹¹³*Id.* at 2019.

¹¹⁴*Id.*

¹¹⁵APA Report, *supra* note 18, at 413.

¹¹⁶*Id.*

¹¹⁷*Id.*

¹¹⁸*Id.*

¹¹⁹Shriqui, *supra* note 91, at 44.

Today, most clinicians reject the rampant megadosing that occurred during the 1980's, prescribing lower doses of antipsychotic medication instead.¹²⁰ Studies, however, indicate the current relapse rate for schizophrenia is three times higher than average.¹²¹ This increase may, in effect, lead to and simultaneously lead to deterioration of the patient's condition increased health care costs.¹²² The high relapse rate can be attributed to the inadequate dosing that results from clinician and patient noncompliance.¹²³ Clinician noncompliance occurs when the clinician fails to recommend prophylaxis, discontinues treatment too soon, and overestimates the risk of complications such as TD. Therefore, the clinician must properly assess the myriad of drug variables, guard against relapse and side effects such as TD, and account for all potential risks in determining whether to prescribe antipsychotic drugs.¹²⁴

TD Treatment Strategies

The APA task force on TD recommends that once a patient's condition worsens, antipsychotic drug use should either be discontinued or a new drug tried,¹²⁵ since for many patients, the presence of TD does not alter the clinician's decision to stop treatment, especially in light of the benefits received.¹²⁶ However, if the patient is only moderately in need of antipsychotic drugs, the risk-benefit analysis might change and the clinician may decide to stop treatment.¹²⁷ Further, a patient with borderline indications for antipsychotic drugs should also receive short, drug-free intervals as a method for unveiling latent TD.¹²⁸

Clinicians should become familiar with the benefits of antipsychotic drug use and monitor for symptoms of TD at least once every three months.¹²⁹ Although TD poses a potential risk for the clinician, in most cases TD is mild and requires no particular treatment other than a gradual

¹²⁰*Id.* at 45.

¹²¹*Id.*

¹²²*Id.*

¹²³*Id.*

¹²⁴*Id.*

¹²⁵*See APA Report, supra* note 18, at 414.

¹²⁶Davis et al., *supra* note 3, at 120.

¹²⁷*Id.*

¹²⁸*Id.*

¹²⁹*APA Report, supra* note 18, at 413.

neuroleptic dose reduction.¹³⁰ Complete discontinuation of antipsychotic drug use, however, is unwarranted since the potential risk of relapse outweighs the benefit of preventing TD.¹³¹

Some patients who display TD symptoms need not discontinue antipsychotic drug use entirely.¹³² These patients should switch to Clozapine or Risperidone because these drugs produce fewer side effects than typical antipsychotic drugs.¹³³ Moreover, one study has indicated that Clozapine and Risperidone may be therapeutically capable of reducing the symptoms of TD.¹³⁴ Additionally, other novel antipsychotic drugs which offer fewer side effects are gradually being introduced into the United States market.¹³⁵

Notably, there is also a growing number of alternative methods of treating TD. The APA task force on TD has indicated that vitamin E,¹³⁶

¹³⁰Shriqui, *supra* note 91, at 45.

¹³¹*Id.* The reader should also be aware that when antipsychotic drugs are discontinued (especially precipitously) in patients who have been treated with the drugs for a year or more, there is potential for a condition called withdrawal supersensitivity psychosis. If left untreated, the psychotic symptoms will usually disappear in several weeks. Unfortunately, the clinician often views this condition as the reemergence of the underlying psychosis and will treat with additional antipsychotic drugs. Restarting antipsychotic drugs with patients with withdrawal supersensitivity psychosis will needlessly prolong the use of antipsychotic drugs and increase the threat of TD. HAYES & YUDOSKY, *supra* note 7, at 915. Also, there are instances where continued antipsychotic therapy is clinically necessary even if the patient has severe tardive dyskinesia. The patient may even die without drug treatment. This situation usually occurs in the elderly who have risks of respiratory failure. *Id.* at 914.

¹³²*Id.*

¹³³Feltner & Hertzman, *Progress in the Treatment of Tardive Dyskinesia: Theory and Practice*, 44 HOSP. COMMUNITY PSYCHIATRY 25 (1993).

¹³⁴There still needs to be more research in this very promising area and some authors disagree with the potential of these drugs to treat TD (or at least question the methodology of the studies that suggest clozapine and risperidone can treat TD). But for an examination of the potential of these two drugs to treat TD, see Lieberman et al., *The Effects of Clozapine on Tardive Dyskinesia*, 158 BR. J. PSYCHIATRY 503 (1991).

¹³⁵These novel antipsychotic drugs include serdolect and zotepine. Clinicians should consider switching to these novel antipsychotics because of the significantly less threat of tardive dyskinesia. Typical antipsychotics still constitute about 85 percent of the prescriptions written for antipsychotic drugs. One problem is that many of these novel antipsychotics are very expensive. But studies have shown that patients are more likely to stay on therapy and stay out of the hospital by taking these novel drugs. This lessening of downstream costs could significantly decrease the financial burden of schizophrenia. A greater educational effort is needed to convince Medicaid officials, state legislators, and other policy makers to permit greater access to novel antipsychotic drugs.

¹³⁶APA Report, *supra* note 18, at 414. For an examination of Vitamin E treatment see Lohr & Caligiuri, *A Double-Blind Placebo-controlled Study of Vitamin E Treatment of Tardive Dyskinesia*, 57 J. CLIN. PSYCHIATRY 167 (1996); Elkashef et al., *Vitamin E in the Treatment of*

ceruletide,¹³⁷ and gamma-linolenic acid¹³⁸ may effectively treat TD.¹³⁹ Pharmacological agents that have received mixed results, yet may nonetheless effectively treat TD include: propranol, clonidine, baclofen, sodium valproate, benzodiazepines, bromocriptine, levodopa, amantadine, verapamil, diltiazem, nifedipine, pindolol, lecithin, naloxone, and isosorbide dinitrate.¹⁴⁰ The use of adjunctive therapies with neuroleptics is not risk-free, and therefore, a risk-benefit analysis that considers the patient's past and current medical condition is necessary.¹⁴¹

PREVENTING TARDIVE DYSKINESIA LITIGATION

Medication-related injuries accounted for 20 percent of the total claims against psychiatrists during the 1980's.¹⁴² A substantial number of these claims involved the use of antipsychotic medication.¹⁴³ According to one commentator, "there is an enormous backlog of cases that is going to plague us for years,"¹⁴⁴ and as such, "the impending flood of [TD] litigation has begun."¹⁴⁵ To date, however, there have been relatively few reported TD-related lawsuits.¹⁴⁶

There are a number of possible reasons why litigation surrounding TD is relatively uncommon. First, chronically ill patients with TD might

Tardive Dyskinesia, 147 AM. J. PSYCHIATRY 505 (1990).

¹³⁷Kojima et al., *Treatment of Tardive Dyskinesia with Ceruletide: A Double-blind, Placebo-controlled Study*, 43 PSYCHIATRY RES. 129 (1992).

¹³⁸Feltner, *supra* note 133, at 30.

¹³⁹*Id.*

¹⁴⁰HAYES & YUDOSKY, *supra* note 7, at 914-15.

¹⁴¹*Id.*

¹⁴²R. SIMON & R. SADOFF, PSYCHIATRIC MALPRACTICE: CASES AND COMMENTS FOR CLINICIANS 106 (1992) [hereinafter SIMON & SADOFF].

¹⁴³*Id.*

¹⁴⁴Baker, *Expect a Flood of Tardive Dyskinesia Malpractice Suits*, CLIN. PSYCHIATRY NEWS (1984), quoted in Appelbaum et al., *Responsibility and Compensation for Tardive Dyskinesia*, 142 AM. J. PSYCHIATRY 806 (1985).

¹⁴⁵Baker, *supra* note 144, at 806.

¹⁴⁶SIMON, *supra* note 16, at 230. As of 1990, Simon's research revealed less than thirty cases (including settlements and unpublished cases) dealing with tardive dyskinesia. The author will cite many of the cases and settlements occurring since 1990 in the next section of the article. The number of cases dealing with TD malpractice after 1990 number less than twenty-five. Many of the recent cases deal with the issue of "right to refuse treatment" and legal defenses like the statute of limitations. Not all of the cases dealing with "right to refuse" or the statute of limitations will be cited. *Id.*

not recognize the opportunity for legal recourse.¹⁴⁷ A relatively high number of severely psychotic patients maintain limited family contacts,¹⁴⁸ and many of these patients are unable to identify the causal connection between their condition and antipsychotic drug use due to factors such as age, type of disability, and lack of information from the clinician.¹⁴⁹ In addition, many of these patients do not wish to publicize their psychiatric condition, and therefore, are reluctant to pursue a claim for fear of public recognition.¹⁵⁰

Causation is another reason why there have been so few TD-related lawsuits reported.¹⁵¹ Failure to document the time and place a patient develops TD is not uncommon, especially since a schizophrenic patient often receives treatment from numerous physicians and mental health workers at different psychiatric facilities.¹⁵² Therefore, to establish a *prima facie* case against a clinician or health care facility, the patient must eliminate the causal connection between TD and other toxic, infectious, neurological, and pre-existing movement disorders.¹⁵³

The latent appearance of TD may further hinder the patient's ability to seek legal recourse.¹⁵⁴ The statute of limitations for malpractice claims, coupled with inevitable discovery rules often bar such claims at the pleading stage.¹⁵⁵ While it may be true that the majority of TD cases demonstrate no signs of malpractice, many prominent psychiatrists believe TD is a condition that appears with regularity.¹⁵⁶ The avoidable TD cases are discouraging to research scientists, especially in light of FDA warnings and guidelines established by the 1992 APA Report on TD.¹⁵⁷

¹⁴⁷SIMON & SADOFF, *supra* note 142, at 110.

¹⁴⁸*Id.*

¹⁴⁹*Id.*

¹⁵⁰*Id.*

¹⁵¹*Id.*

¹⁵²*Id.*

¹⁵³SIMON, *supra* note 16, at 218.

¹⁵⁴*Id.*

¹⁵⁵There are approximately ten cases on record that went for the defense because of the plaintiff's failure to satisfy the statute of limitations.

¹⁵⁶SIMON, *supra* note 16, at 226 (citing Jeste & Wyatt, *Therapeutic Strategies Against Tardive Dyskinesia*, 39 ARCH. GEN. PSYCHIATRY 803 (1982)).

¹⁵⁷*Id.*

A recent 1994 survey indicated that TD continues to stir reactions from both clinicians and clinical administrators.¹⁵⁸ The survey revealed the "denial of [TD], plus the great fear [of] making its risk known, will drive patients off their needed medication [and therefore] clearly continues to get in the way of establishing more rational practice."¹⁵⁹ Studies pertaining to the underrecognition of TD also indicate that physicians at all levels lack concern for TD.¹⁶⁰ Consequently, TD experts emphasize the need to continue educating clinicians and other mental health professionals about the prevention of TD.¹⁶¹

To minimize the occurrence of TD malpractice and alleviate the present "extreme reaction" among clinicians, the entire mental health community must be properly informed as to the nature, benefits, and use of antipsychotic drugs.¹⁶² Education must be directed toward psychiatrists, general practitioners, social workers, psychologists, rehabilitation counselors, nurses, and administrators. The reason for this is simple: mental health facilities currently lack properly trained staff members capable of administering and supervising antipsychotic drug use and assessing TD.¹⁶³ The mental health community must develop

¹⁵⁸Benjamin & Munetz, *CMHC Practices Related to Tardive Dyskinesia Screening and Informed Consent for Neuroleptic Drugs*, 45 HOSP. COMMUNITY PSYCHIATRY 343, 346 (1994).

¹⁵⁹*Id.*

¹⁶⁰Hansen et al., *supra* note 27, at 342.

¹⁶¹*Id.* The author of this article realizes it is not the role of the attorney to give medical advice to the clinician. This article has several functions. First, it attempts to correct many of the factual inaccuracies that many attorneys and judges have concerning TD and antipsychotic drugs. The author believes it is important for an attorney, especially a judge, to understand the medical nuances of TD and antipsychotics because most do not have access to recent medical literature. Most lawyers read legal journals and court cases with inaccurate medical information because the authors of these articles fail to cite recent and accepted medical authority (usually no medical authority is cited). Second, this article may be useful to the social worker, the psychologist, or the nurse who often has to assess patients taking antipsychotic drugs. Third, the article may be useful for the general physician or the general psychiatrist not in an university setting who must administer antipsychotics but may not be expert in their use. Fourth, this article is an attempt to minimize TD litigation by suggesting several medicolegal solutions and commenting on various potential regulatory solutions. This function is the more traditional one for the attorney and is certainly an appropriate topic for both the legal and medical communities. Although the author concedes many in the medical community wonder if "solutions" coming from an attorney do more harm than good. This article will hopefully do more good as it "valiantly" attempts to be sensitive to the concerns of the medical community and attempts to be factually accurate with respect to the medical literature.

¹⁶²Hopefully, this article will alleviate some of the fear in the mental health community regarding TD by explaining the dearth of TD lawsuits and the difficulty of winning a case.

¹⁶³See Benjamin & Munetz, *supra* note 158, at 344.

continuing medical education programs that specifically address TD. Furthermore, since studies suggest that live lectures are an ineffective method of altering clinician prescription habits,¹⁶⁴ videotapes, journal articles, and symposiums may ultimately be more effective.¹⁶⁵

Clinician Liability

Clinician liability for the development of TD is based largely upon the following acts or omissions:¹⁶⁶

- (1) administering dosages of antipsychotic medication for improper reasons, and/or for improper time periods;
- (2) negligent diagnoses which may result in the wrong prescription of antipsychotic medication;
- (3) failure to monitor the patient's condition;
- (4) negligent treatment of TD;
- (5) failure to reduce or discontinue medication;
- (6) polypharmacy, or the dangerous combination of multiple drugs;
- (7) failure to seek expert consultation;
- (8) failure to learn a patient's medical history;
- (9) failure to incorporate risk factors such as age and gender; and
- 10) failure to obtain informed consent prior to administering antipsychotic medication.¹⁶⁷

Notably, the essential function of tort law is to provide a legal remedy for a civil wrong.¹⁶⁸ Negligence principals and methods of recovery likewise provide incentive for people and entities to act in a careful and conscious manner in order to avoid civil liability.¹⁶⁹ While many clinicians carefully administer antipsychotic drugs in an effort to

¹⁶⁴Gardos & Cole, *supra* note 56, at 780.

¹⁶⁵*Id.* See *infra* for a more explicit discussion of specific solutions like monitoring and other regulatory proposals.

¹⁶⁶The following examples of negligent conduct were taken from the author's analysis of the TD case law. For further references to examples of negligence see SIMON & SADOFF, *supra* note 142, at 106; Wettstein, *Tardive Dyskinesia and Malpractice*, 1 BEHAVIORAL SCIENCES AND THE LAW 85, 89 (1983).

¹⁶⁷The author will give an in-depth analysis of the issue of informed consent and the litigation that surrounds informed consent in a subsequent section of this article.

¹⁶⁸Wettstein & Appelbaum, *Legal Liability for Tardive Dyskinesia*, 35 HOSPITAL AND COMMUNITY PSYCHIATRY 992, 993 (1984).

¹⁶⁹*Id.*

prevent TD,¹⁷⁰ prolonged treatment from numerous physicians and institutions tends to minimize the physician's ability to familiarize herself with the patient's medical history, thereby diminishing the overall quality of treatment.¹⁷¹ Because physicians and institutions are often threatened with malpractice claims resulting from their failure to adequately care for and monitor these patients,¹⁷² both groups must consciously defend themselves from allegations of improper delegation of authority, substandard supervision, inadequate training procedures for staff members, and failure to establish appropriate clinician-patient contact.¹⁷³

One reason for the physician's fear of malpractice is the "belegaling" of medicine or the perceived legal intrusion into the medical field.¹⁷⁴ Many physicians become frustrated and subsequently experience a lack of autonomy from the need to adhere to strict defensive medicine, where the primary aim is self-protection from liability in the event of a bad outcome, rather than seeking to ensure the well-being of the patient.¹⁷⁵ This attitude creates an adversarial relationship between the physician and patient, which may ultimately result in poor treatment decisions and increased health care costs.¹⁷⁶ The legal system today must give more deference to the combined professional judgment, competence, and ethics of those in the medical field.¹⁷⁷ In *Youngberg v. Romeo*,¹⁷⁸ the United States Supreme Court declared that significant heed must be paid to the judgments of qualified professionals in determining when reasonable care has been given.¹⁷⁹ Therefore, lower courts must never lose sight that the

¹⁷⁰*Id.* Many clinicians give inadequate dosages because of the threat of TD litigation. The result of this "defensive practice of medicine" is potential relapse and paradoxically an increased threat of malpractice exposure.

¹⁷¹*Id.*

¹⁷²*Id.*

¹⁷³*Id.* at 992-93.

¹⁷⁴*Id.* at 214.

¹⁷⁵GUTHEIL, *supra* note 23, at 211.

¹⁷⁶Defensive medicine nationwide is costing an additional \$15 billion annually, an amount translating to \$1.19 per week for every American. GUTHEIL, *supra* note 25, at 211. Practitioners, the public, and third party insurers all experience the same impact on the price of medical care in the form of additional and possibly unnecessary testing. Fear among physicians and administrators has contributed to a different kind of cost expressed in the unavailability of services in sectors of high-risk exposure. *Id.*

¹⁷⁷Brakel & Davis, *supra* note 6, at 437.

¹⁷⁸457 U.S. 307 (1982).

¹⁷⁹*Id.* at 322-23.

clinician is in the best position to determine the appropriate course of treatment for the patient.¹⁸⁰

The Standard of Care

In malpractice litigation generally, the applicable standard of care can be established by: authoritative treatises such as the Physician's Desk Reference, government regulations and institutional guidelines, expert witness testimony, and studies like the APA 1992 report on TD.¹⁸¹ With respect to TD, the APA guidelines contain several unknowns and qualifiers. For example, the directive that patients on antipsychotic drugs be carefully monitored for TD would probably be given great weight in establishing the applicable standard of care. However, it is yet to be determined whether a physician would be deemed negligent if he failed to administer vitamin E in an attempt to treat TD, failed to utilize the most advanced technology in assessing the patient for TD, and/or administered antipsychotic drugs to treat a condition for which they are not required. Conversely, a violation of government regulations and/or institutional guidelines may serve as *prima facie* evidence of negligence despite the various existing standards of care for TD.¹⁸²

Because there is a degree of uncertainty involved with treating TD, not one, but several possible standards of care are available.¹⁸³ Despite this ambiguity, clinicians, like other specialists, are presently being held to a high standard of care entailing that of a "reasonable specialist," irrespective of community standards.¹⁸⁴

There are many reasonable people in the legal profession who may question the need or wisdom of giving deference to the judgment of the medical professional. Most plaintiffs' attorneys view themselves as defenders of patients wronged by those whom they trusted, and may cast a wary eye at the medical profession. But it is not reasonable to hold an anti-medicine mentality which serves to exacerbate tension between both

¹⁸⁰SIMON, *supra* note 16, at 108. The physician is also in the best position to personally familiarize himself with the patient's condition and medical history. *Id.* Also, it is often difficult for courts to determine the appropriate standard of care and to distinguish bad results from unacceptable behavior because of the variability of practicing patterns. *See* Wettstein, *supra* note 168, at 89.

¹⁸¹*Id.* at 90.

¹⁸²SIMON, *supra* note 16, at 218.

¹⁸³*Id.*

¹⁸⁴*Id.*

communities, and which will ultimately harm the patient. An example of anti-medicine mentality is that of one legal academic who said, "antipsychotic drugs inflict physical and mental harms on a broad scale -- a scale perhaps unprecedented in modern law."¹⁸⁵ This anti-psychiatry and anti-medication attitude among many in both the legal profession and society has increased the potential for psychiatric litigation.¹⁸⁶

Legal literature also indicates a propensity to emphasize the risks of antipsychotic medication, while downplaying its profound benefits.¹⁸⁷ Unfortunately, the majority of legal literature dealing with antipsychotic drugs is not only biased but also factually incorrect.¹⁸⁸ The inaccuracies in legal literature often taint the opinions of judges who rely on law review articles. For example, the judge in *Rennie v. Klein* opined that antipsychotic drugs may cause cancer, although this is, in fact, untrue.¹⁸⁹ Another example of an inaccuracy becoming an established legal fact can be found in *In re the Mental Commitment of M.P.*, where the Indiana Supreme Court asserted that the risk of contracting TD for people taking antipsychotic drugs is 50 percent.¹⁹⁰ One year later, an Illinois Court of

¹⁸⁵Gelman, *Mental Hospital Drugging -- Atomistic and Structural Remedies*, 32 CLEV. ST. L. REV. 221, 223 (1983). Mr. Gelman was the plaintiff's-patient trial and appellate counsel in the infamous right-to-refuse case of *Rennie v. Klein*, 653 F.2d 836 (3d Cir. 1981). Mr. Gelman and the other attorneys who worked on the *Rennie* case should be commended for working to change the grossly negligent environment in the New Jersey state mental hospital system in the 1970's. The psychiatric community in the 1970's was slow to acknowledge the threat of TD. This lack of acknowledgment slowed research, hurt the credibility of the profession, and hurt the patients in these hospitals. But it is dangerous and counterproductive to extrapolate from one grossly negligent situation in the 1970's to the practice of psychiatry today. Such cases today do not support normal institutional psychiatry. One extremely important function of the first part of this article was to show the profound benefits of antipsychotic medicine. Essentially, one could colorfully assert that antipsychotic medicine provided benefits "unprecedented in modern" psychiatry. *Id.*

¹⁸⁶See Davis et al., *supra* note 3, at 121.

¹⁸⁷Brakel & Davis, *supra* note 6, at 436.

¹⁸⁸*Id.* Professor Brakel and Dr. Davis explain in their article that factual inaccuracies occur in legal literature because articles "rely almost exclusively on one another, they merely repeat spurious myths, piling misinformation on top of misinformation." *Id.* at 437. The authors further explain that the original medical information in these law reviews is often inaccurate and misleading. Most legal commentators did not read the original information or could not completely understand the significance of what they read. Another problem is simply the lack of medical articles and textbooks available to most lawyers. *Id.*

¹⁸⁹*Rennie v. Klein*, 476 F. Supp. 1294, 1299 (N.J. 1979).

¹⁹⁰*Id.* at 646.

Appeals cited this case and asserted this inaccurate information.¹⁹¹ The factual errors in these cases are profound and have more than theoretical consequences. The legal principles stemming from these cases may harm the individual patients affected by the ruling, as well as all patients and the mental health professionals who treat them. Also, such errors can adversely influence a clinician's decisional analysis if the physician feels compelled to accept judicial risk perception and not the actual risks involved. Psychiatrists need to use clinical rather than legal criteria in making treatment decisions.

This divergent perception of the risks involved in the treatment of antipsychotic medication is yet another reason for the perceived medical malpractice crisis and the tensions between the medical and legal communities.¹⁹² Thus, judges may tend to view clinicians' treatment decisions as reckless.¹⁹³ The differences in risk perception are magnified by "hindsight bias," as judges in malpractice suits seek outcomes inevitable in retrospect.¹⁹⁴ Judges become more risk adverse because they address treatment decisions retrospectively, while psychiatrists must make treatment decisions prospectively.¹⁹⁵ Judges also become more risk adverse because the side effects of antipsychotic medication are visible in a courtroom, while the benefits of antipsychotic medication are not readily apparent.

The anti-medicine rhetoric often found in legal literature, and the judicial misunderstanding of those medical facts involved in antipsychotic medication and tardive dyskinesia, must be altered. The legal community should be educated on the real risks of antipsychotic medication and TD and must also be informed of the great benefits provided by such

¹⁹¹*In re Orr*, 531 N.E.2d 64, 74 (1988). The accepted prevalence rate for TD is between 10 percent and 20 percent. The incidence of TD is approximately 4 percent per year.

¹⁹²Bursztajn et al., *Medical and Judicial Perceptions of the Risks Associated with Use of Antipsychotic Medication*, 19 BULL. AM. ACAD. PSYCHIATRY LAW 271, 271 (1991). In this study psychiatrists and judges agreed about the probability of TD they would tolerate in order to prevent the recurrence of relapse (50 percent). But the groups diverged in the estimation of the actual probability of TD associated with the continued use of medication. The judges estimated the medication carried a 62.5 percent probability of TD, while the psychiatrists estimated a 25 percent probability of TD. *Id.* at 273. The data indicates that the decision analysis of the two groups differ in many situations where the judges would not treat, the psychiatrists would deem treatment appropriate. *Id.*

¹⁹³*Id.* at 274.

¹⁹⁴*Id.*

¹⁹⁵*Id.*

medication. Judges and juries can learn through expert witnesses the true medical facts in order to make reasoned decisions, and the medical community should approach the problem of TD honestly in order to develop an educational dialogue between the two professions. The communities must be aware of each of the profession's inherent differences, but also acknowledge the communities' real similarities.¹⁹⁶

Although there are profound uncertainties in medical decision analysis, individual and institutional negligence does occur in the administration of antipsychotic medication. An especially controversial issue surrounds the administration of antipsychotic medication to both the mentally retarded and the elderly in nursing homes. *Clites v. Iowa*¹⁹⁷ is the seminal case involving the negligent administration of antipsychotic drugs to a mentally retarded individual. The plaintiff, Timothy, in *Clites* was a patient at the Glenwood Hospital-School, a large residential facility for the

¹⁹⁶One of the most significant differences between the two professions is the tolerance for ambiguity and the manner in which it is handled. Clinicians will always question the ethics of attorneys as long as the adversarial process continues to ignore the uncertainties of the medical decision process. A function of this article is to cause attorneys to be more cognizant of the uncertainties of antipsychotic treatment. But the legal profession is rightly frustrated by the medical profession's assertion that they are the more moral and ethical of the professions. Lawyers, in the eyes of most physicians, are at most amoral. The author has been questioned by several in the medical profession regarding any lawyer's competence in ethical issues. The legal profession allegedly makes all its decisions from some large and secret code (maybe in Louisiana) without any moral or ethical perspective. The author completely rewrote several decisions as a clerk because the decision, although supported by case analysis, was simply not "ethical" according to the judge. Many judicial decisions are not "cut and dried" and the answers cannot often be picked out of some code. There are often two or three almost equally valid decisions-- the very definition of an *ethical* dilemma. Although the author may be venturing into complex and controversial jurisprudential waters, judicial decisions are often based on one's own personal ethical code. Ethical analysis is part and parcel of the average attorney's everyday life. The legal profession is wrong in indicting the mental health system for one or two bad cases; but the medical professional is also wrong in indicting the entire legal profession for several bad experiences.

Several commentators have attempted to distinguish the professions by illustrating that the law is grounded in a deontological perspective while the medical profession is grounded in a teleological perspective. But the law, as illustrated above, is focused not just on rules and procedures, but often acts teleologically as it strives to help each individual reach their highest level of attainment. The medical and legal profession must acknowledge their similarities. Both professions have a high duty to their client or patient, both seek the truth and the attainment of the highest virtue-- justice, and both are concerned about healing (medicine's goal is the healing of the patient's body and the legal profession is concerned about healing the rifts between individuals and healing the "ills" in society).

¹⁹⁷*Clites v. Iowa*, 322 N.W.2d 917 (1982). This case will be explored in detail in the next two sections.

mentally retarded, operated by the State of Iowa.¹⁹⁸ Approximately seven years after Timothy's admission to the hospital, his treating physicians modified his treatment program.¹⁹⁹ Timothy was prescribed major tranquilizers to curb aggressive behavior, and between 1970-1975, he received a "myriad of different tranquilizers, administered in various combinations, under the auspices of several different physicians."²⁰⁰ In 1975, Timothy was diagnosed as suffering from TD, and thereafter filed a negligence action against the hospital. Timothy was ultimately awarded \$385,165 in future medical expenses, and \$375,000 in past and future pain and suffering.²⁰¹

In response to the *Clites* decision, many commentators have promoted the conservative use of antipsychotic drugs with mentally retarded individuals.²⁰² In the mid-1980s, studies revealed that approximately 40 percent of the mentally retarded population received antipsychotic medication, whereas recent studies indicate a significant decrease in antipsychotic drug use among these individuals.²⁰³ This decrease may be the result of an effort to selectively administer antipsychotic drugs to mentally retarded individuals experiencing psychotic problems, and to avoid administering drugs to those individuals merely demonstrating aggressive behavior.²⁰⁴

The improper administration of antipsychotic drugs to the mentally retarded and elderly is troublesome, given the deteriorated physical and/or mental condition of these individuals. A 1980 study revealed that 43 percent of patients in Tennessee nursing homes received antipsychotic medication.²⁰⁵ The excessive use of antipsychotic medication in nursing

¹⁹⁸*Clites*, 322 N.W.2d at 918. Since early childhood, the plaintiff had been diagnosed as mentally retarded due to an unknown prenatal cause. *Id.*

¹⁹⁹*Clites*, 322 N.W.2d at 918.

²⁰⁰*Id.*

²⁰¹*Id.* at 919.

²⁰²See Gualtieri et al., *Tardive Dyskinesia in Mentally Retarded Children, Adolescents, and Young Adults: North Carolina and Michigan Studies*, 18 PSYCHOPHARMACOLOGY BULL. 62, 64 (1982).

²⁰³Intagliata & Rinck, *Psychoactive Drug Use in Public and Community Residential Facilities for Mentally Retarded Persons*, 21 PSYCHOPHARMACOLOGY BULL. 268-77 (1985).

²⁰⁴*Id.*

²⁰⁵Goode, *Antipsychotic Drugs: Regulating Their Use in the Private Practice of Medicine*, 15 GOLDEN GATE U. L. REV. 331, 338 (1985) (citing Ray et al., *A Study of Antipsychotic Drug Use in Nursing Homes: Epidemiologic Evidence Suggesting Misuse*, 70 AM. J. PUBLIC HEALTH 485, 490 (1980)).

homes often occurs because physician-patient contact is limited, medication is overused, and staff turnover is frequent.²⁰⁵ Limited physician-patient contact often requires the delegation of duties to inexperienced nursing staff, which in turn, leads to confusion over dosage levels, telephone errors, and the continuation of medication beyond its clinical usefulness.²⁰⁷ Also, given their lack of psychiatric training in the nursing home, staff members might administer antipsychotic drugs solely to calm the patient, rather than to treat the underlying illness.²⁰³

While education is paramount to the prevention of TD, certain regulatory schemes may also prove valuable.²⁰⁹ Some states require clinicians and staff members to undergo extensive training in the administration of antipsychotic medication.²¹⁰ Such regulations may be useful in preventing TD, without limiting the autonomy of the medical profession.

The implementation of physician-patient contact requirements is another area where statutory regulations may be effective.²¹¹ To illustrate, states could simultaneously require physicians to review a patient's medical history prior to administering a new drug prescription, and to interview patients who take antipsychotic drugs every three to six months per APA guidelines.²¹² Mandates governing physician-patient contact may be the most helpful in the context of a nursing home or mental

²⁰⁵Goode, *supra* note 205, at 340.

²⁰⁷*Id.* (citing Dyer et al., *Geriatrics & Gerontology--The Role of the Pharmacist in a Geriatric Nursing Home: A Literature Review*, 18 DRUG INTELLIGENCE & CLINICAL PHARMACY 428 (P. Lamy ed., 1984)).

²⁰³*Id.*

²⁰⁹There are commentators who question the efficacy of educational efforts for the medical community. See Gelman, *supra* note 193, at 234-240. The essence of this argument is that the cause of TD is not lack of knowledge or carelessness, but the refusal to even acknowledge there is a problem. Consequently, the use of education as a remedy will not solve the problem. Although it may be true that some in the mental health community have difficulty acknowledging the problem of TD, it is through education that these people will understand the realities of TD and the minimal malpractice risk they face if their decisions are informed and documented. *Id.*

²¹⁰Jacqueline Guidry, J.D. et al., *Persons With Developmental Disabilities and Tardive Dyskinesia: A Historical Perspective and an Examination of State Policies Responding to Litigation Questions*, 16 J. PSYCHIATRY & LAW 625, 646 (1988). The federal government also has entered the picture and has allocated large sums of money (via DHEW) toward training programs for pharmacists who could perform clinically-oriented services and promote the rational clinical use of drugs. Goode, *supra* note 205, at 341.

²¹¹Guidry et al., *supra* note 210, at 647.

²¹²*Id.* at 647-49.

institution, since these entities traditionally offer limited physician-patient contact.²¹³

While the benefits of state implemented regulatory schemes are profound, there are also some controversial regulations. One such regulation is the *Jamison-Farabee* consent decree, which requires external review of clinical treatment within three days of antipsychotic drug administration.²¹⁴ Regulations like California's quality assurance system and the *Jamison-Farabee* consent decree have been arguably successful, but they do have setbacks. These mandates often waste clinical resources because the review procedures are expensive and treatment methods are rarely overridden.²¹⁵ Moreover, the patient's condition may worsen during treatment review.²¹⁶ Finally, passive or timid physicians may blindly conform to all guidelines, thereby denying the patient the right to individualized treatment.²¹⁷

One promising area in the prevention of TD involves TD screening and assessment programs. Enhanced methods of instruction and specific clinical examinations should improve TD recognition rates.²¹⁸ Studies suggest that without formal training, even TD assessments from pharmacists, physicians, and psychologists may be inaccurate.²¹⁹ Data also suggests that neither professional group should perform TD screening to the exclusion of the other,²²⁰ especially since a wide range of properly trained medical professionals can accurately screen for TD, although the assessment should be reviewed by a physician.²²¹ Pharmacists and nurses, in particular, perform an integral function in screening for TD because

²¹³*Id.*

²¹⁴*Id.*

²¹⁵See Hargraves et al., *Effects of the Jamison-Farabee Consent Decree: Due Process Protection for Involuntary Psychiatric Patients Treated with Psychoactive Drugs*, 144 AM. J. PSYCHIATRY 188 (1987).

²¹⁶See Brakel & Davis, *supra* note 6, at 455. See also Hargraves, *supra* note 222, at 188.

²¹⁷See Laska et al., *Automated Review System for Orders of Psychotropic Drugs*, 37 ARCH. GEN. PSYCHIATRY 824-27 (1980).

²¹⁸Hansen et al., *supra* note 27, at 343.

²¹⁹Kalachnik & Sprague, *supra* note 27, at 188.

²²⁰*Id.* at 189.

²²¹*Id.*

physicians are often burdened by a myriad of numerous administrative and cost-containment duties.²²²

Regulations requiring TD screening in state hospitals may aid in preventing TD and minimize the likelihood of medical malpractice. A 1986 survey revealed that 61 percent of states required some form of TD assessment for institutionalized patients, but only 18 percent maintained TD assessment policies for individuals residing in community placement.²²³ A 1994 study indicated that 41.3 percent of community placement facilities maintained TD screening policies, but the majority of clinical directors at these facilities stated that TD screening was uncommon.²²⁴ Regrettably, state regulations may have little effect on the actual screening of patients for TD. As one study revealed, only 11.5 percent of psychiatrists affiliated with public hospitals were aware of state regulations on TD risk disclosure.²²⁵ The discouraging results of these studies may be somewhat alleviated, given that 10 percent of hospitals have instituted or altered their TD screening policies since the Benjamin and Munetz survey.²²⁶ Therefore, physicians must never lose sight of the fact that such policies exist as a means to protect both the physician and patient from the negative implications of TD.²²⁷ One method potentially capable of shielding physicians from malpractice liability is the documentation of treatment decisions. One commentator has even declared that documentation of clinical reasoning is the "first commandment of due care."²²⁸ Documentation is necessary to demonstrate awareness of clinical uncertainty and the effort taken to

²²²*Id.* For example, a nurse can conduct a TD assessment and forward the results to a pharmacist if the DISCUS score is over 5. The pharmacist can then review the assessment in terms of drug treatment variables and can forward the assessment to a physician if the case needs more formal diagnostic evaluations. This model may be especially useful in a nursing home or large state mental hospital where physician contact is limited. The reader should note that non-physician assessment is still controversial to some commentators. The use of social workers, case managers or rehabilitation counselors is especially controversial. *Id.*

²²³Guidry et al., *supra* note 210, at 644.

²²⁴Benjamin & Munetz, *supra* note 158, at 346 (noting systematic TD assessment is also now being emphasized through HCFA guidelines).

²²⁵Kennedy & Sanborn, *Disclosure of Tardive Dyskinesia: Effects of Written Policies about Tardive Dyskinesia*, 28 PSYCHOPHARMACOLOGY BULL. 93-100 (1992).

²²⁶Benjamin & Munetz, *supra* note 158, at 346.

²²⁷State or hospital screening policies are also pointless if medical personnel are not adequately trained to give the assessments.

²²⁸GUTHEIL ET AL., *supra* note 25, at 56.

confront such uncertainty.²²⁹ The physician should, therefore, document his method of reasoning as a means to demonstrate the reasonableness of the treatment and that the anticipated benefits of the treatment outweigh the potential harm.²³⁰ Also, without documentation, the clinician is defenseless to judicial hindsight.²³¹ Finally, proper consultation with colleagues is the "second commandment" of due care.²³² While knowledge gained from consultation is beneficial to the patient, it may also reduce TD liability.²³³

Societal recognition and understanding of mental illness is a significant yet indirect method of preventing TD. The public must realize that psychosis is not a sign of weakness, but a devastating disease. Knowledge gained by employers, family members, and friends will undoubtedly aid the schizophrenic's return to society. Also, lobbyists must urge the government and third-party insurance companies to reimburse medical costs while continuing to fund mental illness research. Improved methods of drug and psychosocial treatment for psychotic patients will hopefully prevent relapse and reduce harmful side effects like TD. In addition, there must be societal pressure to fund staff increases and other improvements in large state mental institutions and nursing homes. These changes demand that the medical, legal, and lay communities collaborate in their effort to effectively treat the psychotic patient and prevent TD.

CASE ANALYSIS

Despite the fact that relatively few TD claims ever survive the pleadings stage,²³⁴ clinicians and institutions must nevertheless familiarize themselves with the appropriate standard of care. Therefore, attention must be directed toward those TD claims that have actually survived the pleadings stage, for these cases offer evidence of the requisite standard of care in antipsychotic drug treatment.

²²⁹*Id.* at 58.

²³⁰*Id.*

²³¹*Id.*

²³²*Id.* at 56.

²³³*Id.*

²³⁴There are more TD cases that have been settled, that involved "right to refuse" treatment, and were dismissed because of legal defenses like the statute of limitations. But the author still could only locate approximately 50 cases involving tardive dyskinesia.

The Iowa Court of Appeals decision in *Clites v. Iowa*²³⁵ provides valuable insight into litigation surrounding antipsychotic drug treatment and TD. Faced with the issue of whether high doses of antipsychotic drugs were necessary to curb the patient's aggressive behavior, the court determined the doses were clearly disproportionate to the patient's level of aggression.²³⁶ In support of its decision, the court found the hospital failed to closely monitor the patient for TD, and failed to conduct a physical examination of the patient for three years.²³⁷ In addition, the hospital neither addressed the patient's burgeoning signs of TD, nor altered its treatment program until four years after the patient first showed symptoms of TD.²³⁸ Finally, the court noted that the attending physicians never consulted with specialists to formulate a safe and effective treatment plan for the patient.²³⁹ Based on these facts, the court concluded the hospital was negligent in caring for the patient and upheld a \$760,165 judgment against the hospital.²⁴⁰

Of mutual importance in *Clites*, was the lack of control the hospital maintained over its own staff and drug treatment policies. Because the hospital was severely understaffed, Timothy frequently received antipsychotic medication from non-psychiatrists who were unfamiliar with TD.²⁴¹ *Clites*, therefore, is a classic example of a hospital's negligent care and treatment of a patient receiving antipsychotic drugs.

The *Clites* court also reached several more dubious conclusions that emphasized why the legal community needs to be educated in antipsychotic drug treatment and TD. First, the *Clites* court concluded that the practice of polypharmacy, the concurrent use of multiple drugs, impeded the TD detection process and increased the likelihood of adverse reactions.²⁴² Second, the court considered the clinicians negligent for not providing a "drug holiday."²⁴³ Third, the court concluded the physicians at Glenwood negligently administered antiparkinsonian agents which

²³⁵322 N.W.2d 917 (Iowa Ct. App. 1982) (The appellate court upheld all findings of the trial court including the application of the correct standard of care and the amount of damages).

²³⁶*Clites*, 322 N.W.2d. at 920.

²³⁷*Id.*

²³⁸*Id.*

²³⁹*Id.* The author will discuss the issue of informed consent in *Clites* in the next section.

²⁴⁰*Clites v. Iowa*, 322 N.W.2d 917, 920 (Iowa Ct. App. 1982).

²⁴¹*Id.*

²⁴²*Id.*

²⁴³*Id.*

suppressed the TD.²⁴⁴ Here, the error in the court's argument was that the use of more than one drug is often warranted for treatment of TD, including antiparkinsonian agents, to alleviate severe continuous extrapyramidal symptoms.²⁴⁵ Further, the use of two antipsychotic drugs has no greater effect than a higher dosage of one drug alone.²⁴⁶ Moreover, the court's stipulation of the necessity of "drug holidays," or intermittent treatment, is also controversial. In 1992, the APA stated intermittent therapy is not a viable treatment option for most patients.²⁴⁷

Finally, the court in *Clites* also stated that the use of antipsychotic drugs was designed as a convenience rather than a therapeutic program.²⁴⁸ Much legal commentary contains misleading information like the "fact" that psychiatrists mainly prescribe antipsychotic medication for their own convenience.²⁴⁹ Consequently, *Clites* teaches physicians that they must document that antipsychotic drugs are being used for therapeutic purposes and not for the convenience of the medical staff.²⁵⁰

The Michigan Court of Appeals reached a similar decision in *Faigenbaum v. Oakland Medical Center*.²⁵¹ The plaintiff in *Faigenbaum* was fifty-six year old psychiatric patient suffering from depression and schizophrenia.²⁵² Between the years of 1964 and 1966, the patient was hospitalized for what "may have been manic psychoses" caused by marital difficulties.²⁵³ At this time, she responded favorably to low doses of chlorpromazine.²⁵⁴ The patient was again hospitalized in 1976, suffering from manic-depression, chronic undifferentiated schizophrenia, and hysterical neurosis,²⁵⁵ and she was prescribed chlorpromazine.²⁵⁶

Hospitalized for nearly one year, the patient developed a movement disorder,²⁵⁷ incorrectly diagnosed by a staff neurologist as Huntington's

²⁴⁴*Id.*

²⁴⁵Davis et al., *supra* note 3, at 121.

²⁴⁶SIMON, *supra* note 16, at 227.

²⁴⁷APA Report, *supra* note 18, at 413.

²⁴⁸*Clites v. Iowa*, 322 N.W.2d 917, 921 (Iowa Ct. App. 1982).

²⁴⁹Davis et al., *supra* note 3, at 122.

²⁵⁰*Id.*

²⁵¹373 N.W.2d 161 (Mich. Ct. App. 1985).

²⁵²Gualtieri, et al., *supra* notes 5 at 192.

²⁵³*Id.*

²⁵⁴*Id.*

²⁵⁵*Id.*

²⁵⁶*Id.*

²⁵⁷*Id.*

Chorea, rather than TD.²⁵⁸ As a result of the misdiagnosis, the hospital physicians continued to administer antipsychotic drugs for one year until the patient's family demanded the medication be discontinued.²⁵⁹

In determining whether the hospital was negligent in treating the patient, the *Faigenbaum* court concluded that the hospital physicians incorrectly diagnosed the patient's condition, failed to monitor the patient's condition properly, and negligently continued to administer antipsychotic medication after she displayed clear symptoms of TD.²⁶⁰ The trial court, therefore, awarded a \$1 million judgment in favor of the patient.²⁶¹

Faigenbaum illustrates the importance of recognizing TD in a patient displaying movement disorders pursuant to taking antipsychotic medication. Interestingly, a controversial issue in *Faigenbaum* was whether the patient actually suffered from mental illness. Although the patient was diagnosed as mentally ill in the 1960s, and responded favorably to antipsychotic medication, the trial court determined that she never suffered from mental illness.²⁶²

The United States District Court for the District of Minnesota awarded nearly \$3 million to the plaintiff in *Hedin v. United States*, where the plaintiff received outpatient treatment from a VA hospital for a period of seventeen months, during which time he saw no physician and continued to receive antipsychotic drugs through the mail.²⁶³ In determining whether the VA physicians were negligent in failing to monitor the plaintiff's condition, the court noted that the physicians prescribed an excessive amount of antipsychotic drugs over a prolonged period of time.²⁶⁴ As it turned out, however, the VA ultimately admitted that the prescribed doses were excessive, the plaintiff's condition was not adequately monitored, and the plaintiff's condition had been previously

²⁵⁸*Faigenbaum v. Oakland Medical Ctr.*, 373 N.W.2d 161, 163 (Mich. Ct. App. 185).

²⁵⁹Gualtieri et al., *supra* note 5 at 1920..

²⁶⁰*Faigenbaum*, 373 N.W.2d at 163 (Mich. Ct. App. 1985).

²⁶¹*Id.* The patient also received approximately \$500,000.00 in settlement awards. *Id.* The reader should further note that the appellate court reversed the trial court decision against the state hospital and several of its employees because of governmental immunity. *Id.* at 166. The operation of a mental hospital was considered to be a governmental function entitled to immunity. *Id.* at 164-66.

²⁶²*Faigenbaum*, 373 N.W.2d at 162.

²⁶³No. 5-83-3 (D. Minn. Jan. 4, 1985).

²⁶⁴*Id.* The plaintiff received 600 mg of Thorazine over a four year period.

diagnosed as untreatable.²⁶⁵ Therefore, the sole issue before the court was the amount of damages. The court thereafter awarded the plaintiff nearly \$3 million, including a \$30,000 loss of consortium award to his ex-wife.²⁶⁶ *Hedin* is an interesting case because the VA neither disputed causation, nor raised a contributory negligence defense in light of the plaintiff's addiction to amphetamines.

In *Leal v. Simon*,²⁶⁷ the New York Court of Appeals recommended that a \$2.5 million jury verdict in favor of the plaintiff be reduced to \$1 million.²⁶⁸ The plaintiff in *Leal* was a mentally retarded patient who developed TD at the UCPA facility.²⁶⁹ The defendant-physician ordered a change in the plaintiff's medication from 4 to 2 mg of Haldol, as needed.²⁷⁰ The medication was administered only if the plaintiff became hyper or abusive.²⁷¹ Nearly one month after reducing the patient's Haldol prescription, the plaintiff regressed and became severely self-abusive.²⁷² The defendant-physician thereafter prescribed Haldol in dosages fifteen times higher than the plaintiff's original maintenance amount.²⁷³ The plaintiff soon experienced severe side effects such as the inability to eat, walk, or talk.²⁷⁴

The jury in *Leal* found the physician negligent.²⁷⁵ Expert testimony supported the jury's determination of negligence based on:

- (1) the physician failed to familiarize himself with the plaintiff's medical history;²⁷⁶
- (2) the physician failed to obtain complete medical records and neglected to review the appropriate medical literature and consult with other colleagues with regard to the plaintiff's condition;²⁷⁷ and

²⁶⁵*Id.*

²⁶⁶*Id.* at 18.

²⁶⁷147 A.D.2d 198 (N.Y. 1989).

²⁶⁸*Id.* at 207.

²⁶⁹*Id.* at 199-200.

²⁷⁰*Id.* at 201.

²⁷¹*Id.*

²⁷²*Leal v. Simon*, 147 A.D.2d 198, 201 (N.Y. 1989).

²⁷³*Id.*

²⁷⁴*Id.* at 201.

²⁷⁵*Id.* at 203.

²⁷⁶*Id.* at 204.

²⁷⁷*Leal v. Simon*, 147 A.D.2d 198, 204 (N.Y. 1989).

- (3) the physician was negligent in monitoring the plaintiff's condition, and he should have restricted the plaintiff to an "at-bed-time" dosage of Haldol.²⁷⁸

Interestingly, the physician in *Leal* explained that his decision to reduce the medication was prompted by an impending state audit from the Office of Mental Retardation and Developmental Disabilities of all UCPA programs and physician medical records.²⁷⁹ The audit sought to review whether the UCPA physicians had reduced the overall prescription of antipsychotic medication, a goal of the UCPA facility because of its concern for TD and other side effects.²⁸⁰ The jury noted this defense and found the UCPA facility negligent by adding a handwritten "special finding" in the general verdict.²⁸¹ The appellate court, however, rejected this finding as "surplusage" and "gratuitous" because the jury was "bound to render its verdict in the form prescribed by the court."²⁸² The UCPA facility was, nevertheless, found vicariously liable for the negligent acts of the physician.²⁸³ Consequently, that a physician would alter his method of treatment to avoid administrative interference from a state audit, is one danger that critics of such audits are quick to point out.

There are several other notable TD verdicts. In *Vincent v. Walz*,²⁸⁴ the plaintiff was prescribed Mellaril for menopausal symptoms and maintained the prescription for seven years until she developed symptoms of TD.²⁸⁵ Trial proceeded on the sole issue of damages, after a default judgment was entered against the defendant-physician for failing to answer the complaint in a timely manner.²⁸⁶ The jury ultimately awarded the plaintiff \$1.25 million in damages.²⁸⁷ In *Hudson v. Texas Mental Health & Retardation Center*,²⁸⁸ a Texas court awarded a patient \$820,000.00 in damages after the defendant-physician attempted to treat the chronically depressed patient with Thorazine and Loxitane, even

²⁷⁸*Id.* at 205.

²⁷⁹*Id.* at 201.

²⁸⁰*Id.*

²⁸¹*Id.* at 206.

²⁸²*Leal v. Simon*, 147 A.D.2d 198, 206 (N.Y. 1989).

²⁸³*Id.*

²⁸⁴No. 86-3710 (DeKalb County Sup. Ct., Jan. 14, 1988).

²⁸⁵*Id.*

²⁸⁶*Id.*

²⁸⁷*Id.*

²⁸⁸No. 424,100 (Bexar County Sup. Ct., Jan. 28, 1991).

though she exhibited no signs of schizophrenia.²⁸⁹ The court subsequently reduced the award to \$250,000.00 in compliance with the damages limitations imposed by the Federal Tort Claims Act.²⁹⁰

Finally, in a products liability case, a Texas court in *American Cyanamid Co. v. Frankson*,²⁹¹ found the defendant, Lederle Laboratories, negligent for its design and manufacture of the drug Loxitane.²⁹² The court awarded the patient \$2,195,000.00 in compensatory damages and \$500,000.00 in punitive damages.²⁹³ Interestingly, the court did not find the physicians who administered the medication negligent.²⁹⁴ Nevertheless, while there are relatively few TD verdicts on record, there are several reported settlement agreements.²⁹⁵

In some situations, a patient may develop TD even though the clinician diligently follows the applicable standard of care. There are a number of TD-related cases where the defendant-physician and/or hospital was found not liable even though the patient experienced a "bad result" from the treatment.²⁹⁶ This is common during the pleading stage when, for example, the patient fails to establish proximate cause or the applicable statute of limitations has expired.²⁹⁷ Where the patient fails to inform the

²⁸⁹*Id.*

²⁹⁰*Id.*

²⁹¹732 S.W.2d 648 (Tex. 1987).

²⁹²*Id.* at 651.

²⁹³*Id.*

²⁹⁴*Id.*

²⁹⁵Some of the more noteworthy settlements include: *Snider v. Harding*, No. 84-CV-06-3582 (Franklin Cty. Ct. of Common Pleas August, 1988) where a \$800,000 settlement was reached after a 34 year old male teacher developed TD resulting from negligent treatment of acute psychotic episodes with a medication called Navane; *Urbani v. Yale University School of Medicine*, No. 85-46EBB (Conn. 1986) a \$30,000 settlement was reached even though the 15 year old plaintiff recovered from initial TD symptoms.

²⁹⁶For examples of TD defense verdicts see: *Rivera v. N.Y.C. Health and Hospital Corp.*, No. 27536/82 (New York Sup. Ct. 1988) where the defense argued that plaintiff had only one incidence of torticollis and it was attributable to stress, so Thorazine did not have to be discontinued; *Haney v. Serbin*, No. 90-430 (Montgomery County Court of Common Pleas April 19, 1991) where defense successfully asserted Triavil was appropriately prescribed for depression and other physical problems; *Durell v. Mawhinney*, No. 482189 (San Diego Sup. Ct. July 22, 1988) where defense successfully asserted Haldol was appropriately prescribed; *Cleary v. Eugenia Hospital*, No. 85-11-03593 (Philadelphia County Ct. Common Pleas, December 1991) where defense successfully asserted plaintiff did not suffer from TD but had Huntington's chorea.

²⁹⁷For examples of three of approximately 10 TD cases dealing with the statute of limitations defense see *Barnhart v. United States*, 884 F.2d 295 (7th Cir. 1989); *Bolen v. United States*, 727 F.Supp. 1346 (Idaho 1989); *Gatling v. Perna*, 788 S.W.2d 44 (Tex. 1990).

physician of any known side effects from the medication, contributory negligence may also serve as a bar to complete recovery.²⁹³

INFORMED CONSENT

Under the doctrine of informed consent, a physician must disclose sufficient information that would allow a patient to make an "informed" decision about a proposed treatment.²⁹⁹ In *Canterbury v. Spence*,³⁰⁰ the United States District Court for the District of Columbia explained that, "true consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each."³⁰¹ At least one court has indicated that "every person has a right to determine and control what is to be done to his or her body; and a surgeon who performs an operation without his patient's consent commits [a battery] for which he is liable for damages."³⁰² The requirement of informed consent seeks to promote, among other things, greater patient autonomy, the preservation of the patient's livelihood, self-regulation and rational decision making by the physician, and greater public involvement in medical decision making.³⁰³

Physician liability for lack of informed consent is premised on two legal theories: (1) the intentional tort of battery; and (2) negligence. In the context of TD litigation, a patient might allege battery, since the failure to disclose potential side effects of antipsychotic drug use is tantamount to treatment without consent.³⁰⁴ Similarly, a TD patient might allege negligence in the event she was not adequately informed of the risks and implications necessary to make an informed decision as to whether to submit to such treatment.³⁰⁵ In the latter situation, the patient asserts that, "had the physician disclosed the risk and implications of antipsychotic drug use, I would not have consented to the treatment." Moreover, a claim based on lack of informed consent does not require that the physician provide the "best" or "optimal" treatment; rather, a lack of

²⁹⁸See *Tisdale v. Johnson*, 339 S.E.2d 764 (Ga. 1986).

²⁹⁹SIMON & SADOFF, *supra* note 142 at 101.

³⁰⁰464 F.2d 772, 780 (D.C. Cir. 1972).

³⁰¹*Id.*

³⁰²*Schoendorff v. New York Hospital*, 105 N.E. 92, 93 (1914).

³⁰³SIMON & SADOFF, *supra* note 142, at 102.

³⁰⁴*Id.*

³⁰⁵*Id.*

informed consent claim merely requires the physician to provide treatment consistent with the standard of care.³⁰⁶

Three basic elements comprise the informed consent requirement:

- (1) knowledge of the risks;
- (2) patient competency; and
- (3) voluntariness of the consent.³⁰⁷

Traditionally, the scope of disclosure has been determined by "what a reasonable medical practitioner would disclose under the same or similar circumstances."³⁰⁸ This standard was challenged in 1972 when the court in *Canterbury v. Spence*³⁰⁹ rejected the reasonable practitioner approach, adopting instead the objective or "reasonable patient" approach.³¹⁰ This approach, according to the court, requires the physician to disclose all known "material risks" to the patient.³¹¹ A risk is therefore material, the court stated, "when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether to forego the proposed therapy."³¹² The court rejected the substantive standard by stating that a standard based upon the opinions of a physician could not regulate patient rights.³¹³

Significantly, *Canterbury* does not stand for the proposition that a physician is required to disclose every risk that is theoretically possible.³¹⁴ Rather, the court indicated the category of risks the physician should communicate "is no broader than the complement he could communicate."³¹⁵ The duty to disclose, the court determined, may extend to any risk the physician has actual knowledge of, excluding of course,

³⁰⁶*Id.* at 99.

³⁰⁷Mills et al., *Consent and Liability with Neuroleptics: The Problem of Tardive Dyskinesia*, 8 INT. J. LAW PSYCHIATRY 243, 248 (1986).

³⁰⁸Natanson v. Kline, 350 P.2d 1093 (Kan. 1960).

³⁰⁹464 F.2d 772 (D.C. Cir. 1972).

³¹⁰*Id.*

³¹¹*Id.*

³¹²*Id.* at 786 (citing Waltz & Scheuneman, *Informed Consent To Therapy*, 64 N.W.U.L. REV. 628, 640 (1970)).

³¹³SIMON & SADOFF, *supra* note 142, at 102.

³¹⁴*Id.* at 103.

³¹⁵*Canterbury v. Spence*, 464 F.2d 722, 786, n.84 (D.C. Cir. 1972) (referring to *Block v. McVay*, 126 N.W.2d 808, 812 (S.D. 1964)).

those risks that the physician is unaware exist.³¹⁶ Thus, nondisclosure of an unknown risk, according to the court, "does not, strictly speaking, present a problem in terms of the duty to disclose although it very well might pose problems in terms of the physician's duties to have known of it and to have acted accordingly."³¹⁷

Physicians should therefore incorporate five general categories of disclosure into their method of treatment:

- (1) the diagnosis;
- (2) an overview of the proposed treatment;
- (3) a description of the most likely risks and benefits of the proposed treatment;
- (4) alternative treatments, if any; and
- (5) the prognosis.³¹⁸

Treatment posing great risks obliges the physician to disclose even relatively remote risks, especially if alternative therapies are available.³¹⁹ Consequently, because of its relatively high prevalence/incidence rates, and its potentially permanent nature, physicians have both an ethical and legal obligation to disclose the risks of TD to a patient.

Patient competency is another element of informed consent.³²⁰ The law presumes a patient to be competent unless judicially determined otherwise.³²¹ Courts employ four standards to determine patient competency:

- (1) ability to communicate choice;
- (2) whether the patient comprehends the information provided to him;
- (3) recognition of alternative forms of treatment; and
- (4) ability to make rational decisions.³²²

While most lawyers define patient competency in cognitive terms, courts tend to focus on the patient's ability to communicate choice and the level

³¹⁶*Canterbury*, 464 F.2d at 786, n. 84 (referring to Waltz & Scheunceman, *Informed Consent To Therapy*, 64 N.W.U.L. REV. 628, 630-35 (1970)).

³¹⁷*Id.*

³¹⁸SIMON & SADOFF, *supra* note 142, at 103-04.

³¹⁹Wettstein, *supra* note 168, at 95.

³²⁰SIMON & SADOFF, *supra* note 142, at 104.

³²¹*Id.*

³²²*Id.*

of comprehension the patient displays.³²³ Nevertheless, true informed consent is generally believed to exist when the patient makes a rational decision to undergo treatment after being fully apprised of the risks and benefits of the given treatment.³²⁴

Determining patient competency is critical to the administration of antipsychotic drugs. With respect to an incompetent patient, the physician should obtain consent by means of a proxy as soon as clinically possible.³²⁵ If a patient's competency level is questionable, commentators recommend that the psychiatrist obtain consent from both the patient and a proxy.³²⁶ Also, in the event a patient experiences prolonged psychosis, the physician should seek a judicial declaration of competency, or lack thereof.³²⁷ The physician must acknowledge a competent patient's right to refuse antipsychotic medication.³²⁸ Legal and ethical problems often arise in those situations where the patient, who is borderline competent, refuses antipsychotic medication for fear of developing TD.³²⁹

The final element of informed consent is voluntariness. Here, the patient should never be coerced into accepting or rejecting treatment, either by threats of punishment or promises of favored treatment.³³⁰ One example of coercion is when physicians condition television privileges upon taking antipsychotic medication.

There are four potential exceptions to the requirement of informed consent:

- (1) incapacity;

³²³*Id.*

³²⁴*Id.*

³²⁵Mills, *supra* note 307, at 249.

³²⁶*Id.*

³²⁷*Id.* From a liability standpoint, the physician should never "assume" the patient is competent.

³²⁸SIMON, *supra* note 16, at 225. A more detailed discussion of the "right to refuse" issue and its relationship to TD and antipsychotic medication will be done in the next section. This is a very complex issue and proper exploration is impossible in the scope of this article. The right to refuse medication or treatment is a foundation for informed consent and has the same philosophical underpinnings. The tension between autonomy and paternalism runs to the heart of the right to refuse issue. Further, the problem of TD exacerbates this tension in the right to refuse antipsychotic medication. Again, much of this tension could be alleviated if the medical and legal community placed primacy on the ethical value of respect for persons in medical and legal treatment analysis. *Id.*

³²⁹*Id.*

³³⁰SIMON & SADOFF, *supra* note 142, at 105.

- (2) emergency;
- (3) therapeutic privilege; and
- (4) waiver.³³¹

The patient, for example, may request that the physician not disclose any potential risks of treatment.³³² The physician might invoke therapeutic privilege if disclosure of an uncommon risk will place undue stress upon the patient and thereby cause the patient to refuse treatment.³³³ There should be little reason, however, to use the therapeutic privilege exception because any patient can gradually be exposed to stressful information at repeated intervals of time.³³⁴

Physicians must treat informed consent as an ongoing process rather than a limited method of disclosure occurring at a single point in time.³³⁵ This view is especially appropriate for psychiatrists treating patients with schizophrenia. A 1982 study revealed that many schizophrenic patients, previously informed of the risk of TD, lacked the capacity to retain the information necessary to make an informed decision.³³⁶ The patients did not appear to comprehend the nature and implications of the consent form.³³⁷ In light of this, the study recommended continuous sharing of information between the physician and patient.³³⁸

Another controversial aspect of informed consent, especially in the context of TD, is determining which staff member should disclose the risks and implications of treatment to the patient. Absent hospital guidelines, informal delegation, often referred to as "buck-passing," may occur.³³⁹ Moreover, in those situations where the patient seldomly communicates with the physician, the likelihood of inadequate disclosure is profound.³⁴⁰ Therefore, and as a matter of good practice, the hospital should educate staff members on the pertinent issues, elements, and

³³¹*Id.* at 103.

³³²*Id.*

³³³*Id.*

³³⁴*Id.* at 101.

³³⁵Latimer, *supra* note 26, at 53.

³³⁶Munetz et al., *Tardive Dyskinesia and Informed Consent: Myths and Realities*, 10 BULL. AM. ACAD. PSYCHIATRY LAW 77, 88 (1982).

³³⁷*Id.* at 86.

³³⁸*Id.*

³³⁹Munetz, *Overcoming Resistance to Talking to Patients About Tardive Dyskinesia*, 36 HOSPITAL COMMUNITY PSYCHIATRY 283, 284 (1985).

³⁴⁰*Id.*

exceptions to informed consent, and encourage members to collaborate in their effort to disclose relevant information to the patient.³⁴¹

Determining the proper method of disclosure is yet another controversial aspect of informed consent. A 1985 study indicated that therapists prefer a stringent disclosure program that incorporates a risk/benefit evaluation of antipsychotic medication.³⁴² This may include, among other things, the periodic administration of an AIMS examination, questionnaires used to gauge patient knowledge before and after disclosure, and patient medication instruction sheets.³⁴³ Group study is another effective disclosure method. Here, patients can express their concerns with TD, as opposed to the burden of psychosis.³⁴⁴

The same 1985 study also found that oral consent used in conjunction with a stringent disclosure program, had a greater impact on the patient than a written consent form.³⁴⁵ In fact, in a 1991 report, the APA expressed dissatisfaction with the use of written consent forms as a method of disclosing the risks and implications of antipsychotic drug use.³⁴⁶ Careless application of written consent forms, commentators suggest, stifles communication between the patient and physician,³⁴⁷ which may increase malpractice exposure, especially since the patient's decision to undergo treatment was heavily influenced by sources other than herself.³⁴⁸

Some commentators argue that use of a written consent form detracts from the benefits of joint decision making between the patient and physician.³⁴⁹ These individuals urge physicians to reject the written consent form in favor of a non-threatening, verbal explanation of the risks and benefits of antipsychotic medication.³⁵⁰

Clinicians may nevertheless reject the findings of the APA Report for the following reasons:

³⁴¹*Id.*

³⁴²*Id.* at 286.

³⁴³*Id.*

³⁴⁴*Id.*

³⁴⁵*Id.* There is an ongoing debate over which method of consent is more effective, oral or written consent.

³⁴⁶*APA Report, supra* note 18, at 414.

³⁴⁷*Id.*

³⁴⁸Benjamin & Munetz, *supra* note 163, at 345.

³⁴⁹*Id.*

³⁵⁰SIMON, *supra* note 16, at 224.

- (1) state mandated use of written consent forms;
- (2) convenience;
- (3) corporate policy; and
- (4) lack of familiarity with other types of disclosure.³⁵¹

Irrespective of the rationale behind rejecting the APA's findings, clinicians must realize that courts can invalidate the written consent form in light of public policy considerations such as unconscionability, vagueness, patient incompetence, and even duress.³⁵²

In a 1985 comparative analysis between TD patients informed of the risks and benefits of antipsychotic drug treatment through a written consent form, and TD patients informed verbally, the patients who received verbal disclosure retained more information within two months after testing than the other patients.³⁵³ Accordingly, clinicians who are required to use written consent forms should attempt to incorporate verbal disclosure into the clinician-patient relationship. A therapeutic alliance between the clinician and patient would place the clinician "next to" rather than "across from" the patient.³⁵⁴ Because malpractice litigation is often triggered by physician arrogance, indifference, insensitivity, and the "malignant synergy of a bad outcome in the context of bad feelings,"³⁵⁵ continuous communication between the clinician and patient may reduce these "bad feelings" and counter the terrible experience of suffering from schizophrenia all alone. Patience and respect for the patient is likewise a necessary component of informed consent because many psychotics require additional time to develop a trusting relationship with the physician.³⁵⁶ Also, psychological support may enable a borderline competent patient "to conduct a risk-benefit analysis sufficient to give a valid consent to treatment."³⁵⁷

The last controversial issue surrounding informed consent is determining when disclosure should occur. The APA has indicated the

³⁵¹Benjamin & Munetz, *supra* note 158, at 346.

³⁵²Wettstein, *supra* note 168, at 101. Written consent forms are often extensive and quite difficult to comprehend because they are written at a post-graduate level.

³⁵³Munetz & Roth, *Informing Patients About Tardive Dyskinesia* 42 ARCH. GEN. PSYCHIATRY 866, 869 (1985).

³⁵⁴GUTHEIL ET AL., *supra* note 25, at 80.

³⁵⁵*Id.* at 82.

³⁵⁶SIMON, *supra* note 16, at 224.

³⁵⁷*Id.*

“patient or legal guardian should be informed of the risk [of TD] as soon as clinically feasible, especially in cases when the patient [demonstrates] signs of the condition and the physician is considering resuming medication.”³⁵⁸ The phrase “as soon as clinically feasible” has sparked debate among commentators because of its lack of clarity. Several commentators argue that the risks and benefits of antipsychotic drug use should be disclosed prior to treatment, unless an emergency or therapeutic privilege exists.³⁵⁹ Thus, failure to disclose prior to treatment may increase a patient’s cumulative intake of drugs, thereby increasing the likelihood of a malpractice claim against the physician.³⁶⁰ If the clinician must resume the administration of antipsychotic drugs to a patient with TD, there is no justifiable delay, absent an emergency.³⁶¹

The question often arises as to when the risks and implications of antipsychotic drug use should be disclosed to an acutely psychotic patient. In most cases, acute psychosis will remit within two months and at that point, there should be full disclosure and patient consent.³⁶² Nevertheless, as a safety measure, the physician should always document why there was no disclosure and/or patient consent prior to treatment, or within a relatively short time thereof.

There still remains widespread physician resistance to informed consent guidelines.³⁶³ Some physicians characterize informed consent as a “legalistic fiction” because they believe a fully-informed patient might refuse necessary treatment if provided with “too much” information, thereby reducing the physician’s ability to treat illnesses such as schizophrenia.³⁶⁴ To the contrary, other studies have suggested that patients are rarely “frightened out of treatment” after receiving full disclosure of the risks and implications of antipsychotic drug treatment and TD.³⁶⁵ According to these studies, TD disclosure increases the level of trust between the patient and physician, and mitigates the impact when alarming information is conveyed to the patient.³⁶⁶

³⁵⁸ *APA Report*, *supra* note 18, at 414.

³⁵⁹ *SIMON*, *supra* note 16, at 221. See also *Mills*, *supra* note 307, at 245.

³⁶⁰ *SIMON*, *supra* note 16, at 221.

³⁶¹ *Id.* at 224.

³⁶² *Id.* at 132.

³⁶³ *Munetz*, *supra* note 339, at 283.

³⁶⁴ *Wettstein*, *supra* note 168, at 97.

³⁶⁵ *Munetz*, *supra* note 339, at 283.

³⁶⁶ *Id.* at 284.

It must be emphasized that a mentally ill patient is not per se unable to comprehend the risks and implications of antipsychotic drug treatment.³⁶⁷ A 1985 study indicated that mentally ill patients are nearly as capable of appreciating the risks and implications of antipsychotic drug as other patients.³⁶⁸ A 1983 study similarly revealed that while acute schizophrenic patients are less likely to comprehend the risks and implications of antipsychotic drug treatment, post-acute schizophrenic patients respond well to detailed, yet informal, discussions concerning the risks of antipsychotic drug use.³⁶⁹

Lack of informed consent is most acute in state hospitals and nursing homes.³⁷⁰ A 1988 study involving ninety-one elderly patients, 44 percent of whom were taking antipsychotic drugs, revealed a genuine lack of informed consent.³⁷¹ The same study also revealed that 82 percent of the patients in a state mental hospital clearly demonstrated a lack of familiarity with the risks and benefits of antipsychotic drug treatment, and were therefore, unable to properly consent to the treatment.³⁷²

Unfortunately, not even the most conscientious physicians and careful institutional regulations can overcome all the barriers to providing informed consent to many schizophrenic patients. These patients have difficulty processing information, they have lower literacy skills, and

³⁶⁷SIMON, *supra* note 16, at 222.

³⁶⁸Stanley et al., *Psychopharmacologic Treatment and Informed Consent. Empirical Research*, 21 PSYCHOPHARMACOLOGY BULL. 110, 113 (1985). This study did indicate that schizophrenic patients have more difficulty in the consent process than patients with major affective disorders. But the study did show that factors other than medicated or non-medicated and psychiatric or non-psychiatric are more important in the consent process. Factors such as verbal ability and practical reasoning are more indicative of competency to give informed consent. *Id.*

³⁶⁹See Marder et al., *A Comparison of Patients who Refuse and Consent to Neuroleptic Treatment*, 140 AM. J. PSYCHIATRY 470 (1983).

³⁷⁰A 1985 study indicated that 50 percent of community placement facilities administered informed consent. A recent study completed in 1994 indicated 73.8 percent had policies of obtaining informed consent, 73.7 percent used a consent form, 17.8 percent used a checklist, 73.7 percent used documentation of a verbal discussion, 5.9 percent used a patient information sheet, 61 percent used a combination of techniques, and 56.8 percent incorporated a consent form and documented discussion. Benjamin & Munetz, *supra* note 163, at 345. Unfortunately, another study indicated that only 11.5 percent of public hospital psychiatrists were aware of state policies regarding risk disclosure. See Kennedy & Sanborn, *supra* note 232, at 93.

³⁷¹Beck, *Determining Competency to Assent to Neuroleptic Drug Treatment*, 39 HOSPITAL COMMUNITY PSYCHIATRY 1106, 1110 (1988).

³⁷²*Id.*

many schizophrenics' primary focus is to avoid relapse at all costs.³⁷³ Other barriers to informed consent exist because some psychotic patients deny they have TD, and many of the elderly have no family to provide proxy consent.³⁷⁴

It is important for physicians to document the patient's actual understanding and consent in the medical record to further protect herself from legal liability alleging lack of informed consent.³⁷⁵ The APA's Task Force on TD has stated that "careful documentation of the disclosure process is recommended. Further, the clinician should note what she told the patient, what the patient said and understood, and how a treatment decision was reached."³⁷⁶ One commentator cited the following defenses that can be used to defend a malpractice claim alleging lack of informed consent:

- (1) common knowledge of the risk;
- (2) waiver;
- (3) therapeutic privilege;
- (4) a written consent form;
- (5) the fact that a reasonable person would have undergone the treatment anyway;
- (6) no expert medical testimony; and
- (7) insubstantial risk.

While TD litigation stemming from the lack of informed consent is still relatively uncommon, the majority of reported cases involve mentally retarded and elderly patients.³⁷⁷ In *Clites*, the court determined the physician failed to properly inform Timothy's family of the risk of TD.³⁷⁸ The parents, as proxy, were never informed of the potential side effects of the prolonged use of major tranquilizers, nor did they consent to the use.³⁷⁹ The industry standard, according to the court, required Timothy's parents to be apprised of the dangers and benefits of the prescribed treatment

³⁷³Munetz & Roth, *supra* note 353, at 870.

³⁷⁴Munetz, *supra* note 339, at 284.

³⁷⁵Davis et al., *supra* note 3, at 124.

³⁷⁶APA Report, *supra* note 18, at 414.

³⁷⁷*Id.*

³⁷⁸*Clites v. Iowa*, 322 N.W.2d 917, 923 (Iowa Ct. App. 1982).

³⁷⁹*Id.* at 922.

program.³⁸⁰ Also, the court indicated that while consent need not always be in writing, the physician must make "reasonable disclosure to the patient of the nature and probable consequences of the suggested or recommended treatment."³⁸¹ The court further indicated that even if a physician is not required to describe in detail all possible risks of the treatment, as this may alarm the patient, the physician should, nevertheless, disclose all material risks.³⁸² Finally, the *Clites* court rejected the notion of "implied consent."³⁸³ The court acknowledged that although Timothy's parents may have known Timothy was receiving medication, "they were not informed of the risks attendant to the treatment program."³⁸⁴ Because the parents were ignorant of the potential dangers of the treatment program, the court concluded there was "no basis for saying [the parents] impliedly consented to the administration of major tranquilizers by their failure to object."³⁸⁵ The court, therefore, upheld the damages award against the hospital.³⁸⁶

The Supreme Court of Texas similarly addressed the issue of informed consent in *Barclay v. Campbell*, where plaintiff ("Milton") developed TD after he was prescribed neuroleptic drugs by the defendant-physician in an effort to treat his mental illness.³⁸⁷ Thereafter, Milton brought a malpractice claim against the physician, alleging the physician negligently prescribed the neuroleptic drugs and failed to disclose the risks associated with the drugs.³⁸⁸ On the issue of informed consent, the court determined the focus was not whether Milton could have been influenced in making a decision to give or withhold consent to the procedure had he known of the risk. Rather, the issue was "whether a reasonable person could have been influenced in making a decision to give or withhold consent to the procedure had he known of the risk."³⁸⁹ If a reasonable person could have been influenced in making a decision, Milton, the court

³⁸⁰*Id.* at 922-23.

³⁸¹*Id.* at 923.

³⁸²*Id.*

³⁸³*Clites v. Iowa*, 322 N.W.2d 917, 923 (Iowa Ct. App. 1982).

³⁸⁴*Id.*

³⁸⁵*Id.*

³⁸⁶*Id.* One interesting aspect of *Clites* is that the hospital asked the parents' permission to use their son's picture at a presentation, but did not think it necessary to ask for their permission in using antipsychotic drugs. *Id.*

³⁸⁷704 S.W.2d 8 (Tex. 1986).

³⁸⁸*Id.*

³⁸⁹*Id.* at 10.

determined, "was also entitled to be warned of the risk."³⁹⁰ Based on those facts, the court concluded that the issue of informed consent should have been submitted to the jury.³⁹¹

Both *Clites* and *Barclay* support the proposition that courts are visibly concerned with the lack of informed consent in antipsychotic drug treatment. As more of these cases are litigated, physicians and lawyers alike, will become more familiar with the appropriate disclosure and patient consent guidelines applicable to antipsychotic drug treatment, improving the overall standard of care in antipsychotic drug treatment.

THE RIGHT TO REFUSE TREATMENT

A patient's right to refuse antipsychotic drug treatment is a controversial issue which causes much strife between the medical and legal communities.³⁹² As the risks of antipsychotic drug use become more identifiable, the right to refuse treatment issue will gain paramount importance in the context of antipsychotic drug treatment.³⁹³ The past abuse of antipsychotic drugs in the 1960s and 1970s is a vivid example of why there should be safeguards governing a patient's right to refuse medication.³⁹⁴ Whether a patient has a right to refuse treatment often incorporates constitutional implications such as:

- (1) freedom of speech;
- (2) prohibition against cruel and unusual punishment;
- (3) due process guarantees;
- (4) equal protection;
- (5) freedom of religion; and
- (6) the right to privacy.³⁹⁵

Legal commentators attribute the high risk of TD as the main reason why competent patients, institutionalized or not, deserve the right to refuse

³⁹⁰*Id.* at 10-11.

³⁹¹*Id.* at 11.

³⁹²Perr, *Refusing Treatment --Who Shall Decide?* 10 BULL. AM. ACAD. PSYCHIATRY LAW 233, 235 (1982).

³⁹³*Id.*

³⁹⁴B. WEINER & R. WETTSTEIN, LEGAL ISSUES IN MENTAL HEALTH CARE 120 (1993).

³⁹⁵*Id.* at 125. See also Perr, *supra* note 392, at 311.

antipsychotic medication.³⁹⁶ The same holds true for decisions made by incompetent patients. However, in the latter situation, the patient's decision to refuse antipsychotic medication should be subject to judicial review.³⁹⁷ Advocates of the right to refuse medication have adopted the rationale espoused in *Rogers v. Okin*,³⁹⁸ where the United States District Court for the District of Massachusetts commented on the constitutional implications of a patient's right to refuse mind-altering psychotic drugs:

The concept of a right of privacy also embodies First Amendment concerns. It is clear from the evidence in this case that psychotic medication has the potential to affect and change a patient's mood, attitude, and capacity to think At stake is the [sic] fundamental question as to whether the state may impose once again on the privacy of a person, already deprived of freedom through commitment by forcibly injecting mind-altering drugs into his system in a non-emergency situation.³⁹⁹

The *Rogers* court further stated:

The right to produce a thought -- or refuse to do so -- is as important as the right protected in *Roe v. Wade* to give birth or abort. Implicit in an individual's right to choose either abortion or birth is an underlying right to think and decide. Without the capacity to think, we merely exist, not function. Realistically, the capacity to think and decide is a fundamental element of freedom.⁴⁰⁰

The legal community did well exposing the abuses, neglect, and ignorance in the state hospital at the time. Its goal of improving patient care and defending patients' rights/liberty was laudable, but the legal community went too far and paradoxically diminished psychotic patients' liberty and quality of care. Why do patients refuse medication and what should the legal and medical communities do when refusal of antipsychotic medication occurs?

³⁹⁶WEINER & WETTSTEIN, *supra* note 394, at 131.

³⁹⁷*Id.*

³⁹⁸478 F. Supp. 1342 (D. Mass. 1979).

³⁹⁹*Id.* at 1366.

⁴⁰⁰*Id.*

Patients who experience delusions often refuse antipsychotic medication as a result of the *symptomatic* nature of their illness.⁴⁰¹ Many of these patients possess an unrealistic fear of the effects of antipsychotic drug treatment, often associating the administration of depot medication as a form of bodily assault.⁴⁰² While legal advocates must respect a competent patient's decision to forego antipsychotic drug treatment, the same does not necessarily hold true for patients who experience delusions, as many of these patients expressly deny the very existence of their illness.⁴⁰³ Therefore, the decision not to administer antipsychotic drugs to a patient who experiences delusions must be, to a large part, based on medical information, usually to the exclusion of the patient's delusion-induced requests.⁴⁰⁴

Other patients temporarily refuse medication because of problems with the staff or their own family.⁴⁰⁵ The voluntary patient has the right to leave the hospital if she does not wish to cooperate with the prescribed treatment. But the "well-meaning" legal advocate who defends the "right" of an involuntary patient to refuse antipsychotic treatment ventures into dangerous territory if not in possession of all the medical facts or if the lawyer does not understand the nuances of the treatment plan.⁴⁰⁶

When medication is given, the patient can recover, go home, and have her liberty restored.⁴⁰⁷ After the patient regains competency then the patient can make an informed decision whether or not to continue taking medication. The legal community should understand that involuntary patients were committed because they posed a risk to themselves and/or the community and were unable to rationally participate in any treatment decision.⁴⁰⁸ Legal advocates must begin to appreciate how illogical it is

⁴⁰¹Brakel & Davis, *supra* note 6, at 467.

⁴⁰²WEINER & WETTSTEIN, *supra* note 394, at 131.

⁴⁰³*Id.*

⁴⁰⁴Courts in their zeal to prevent past abuses may be depriving patients of the best treatment available. As explained earlier in the article, judges may be relying on heavily biased and inaccurate law review articles in their determinations of the risk/benefits of antipsychotic drugs. An important function of this article is to help eradicate any biases, prejudices, or faulty information regarding antipsychotic drugs and their risk/benefits. Although reasonable people may disagree on certain issues surrounding the right to refuse antipsychotic medication, it is unreasonable not to be educated and objective regarding the medical information.

⁴⁰⁵WEINER & WETTSTEIN, *supra* note 394, at 131.

⁴⁰⁶See Brakel & Davis, *supra* note 6, at 441.

⁴⁰⁷*Id.* at 450.

⁴⁰⁸*Id.* at 442.

to commit a patient involuntarily and then assert the patient has the "right" to refuse the treatment necessary to regain both competency and liberty.

Those who advocate the "right to refuse" treatment seek to eliminate institutionalization as a factor in determining whether to acknowledge the patient's rejection of treatment.⁴⁰⁹ To the extent these advocates are concerned, a competent, yet institutionalized, patient's rejection of antipsychotic medication must be respected.⁴¹⁰ If the institutionalized patient is incompetent, a judicial hearing should be held to determine the patient's best interests and whether the patient would in fact benefit from antipsychotic drug treatment.⁴¹¹ Because the court in the latter situation is the ultimate decision maker, disputes often arise concerning the ability of a judge to implement final orders on technical medical issues like TD.⁴¹²

A patient's right to refuse treatment has impacted the medical community in several other ways. A 1990 study, for example, documented the purported impact of *Rivers v. Katz*,⁴¹³ a 1986 New York Appellate Court decision, which held that in a nonemergency situation, a patient previously adjudged legally unable to make an informed decision, may be compelled to submit to antipsychotic drug treatment, irrespective of the fact the patient does not wish to undergo such treatment.⁴¹⁴ The study revealed that competency hearings increased the average amount of time necessary to resolve a treatment dilemma.⁴¹⁵ While the resolution of refusal-disputes occurring in a private hospital averaged ten days prior to the *Rivers* decision, the study revealed that the same disputes averaged a thirty-one day resolution period after *Rivers*.⁴¹⁶ Consistent with these findings, the study also revealed that while resolution of refusal-disputes at a public hospital averaged twenty-one days pre-*Rivers*, the same disputes averaged a sixty-eight day resolution period post-*Rivers*.⁴¹⁷ The

⁴⁰⁹ Appelbaum, *The Right to Refuse Treatment with Antipsychotic Medications: Retrospect and Prospect*, 145 AM. J. PSYCHIATRY 413, 416 (1988).

⁴¹⁰ *Id.* This is the same view articulated by the court in *Rogers v. Okin*, 478 F. Supp. 1342 (D. Mass. 1979).

⁴¹¹ *Id.*

⁴¹² *Id.*

⁴¹³ 495 N.E.2d 337 (N.Y. 1986).

⁴¹⁴ *Id.*

⁴¹⁵ Ciccone et al., *Right to Refuse Treatment: Impact of Rivers v. Katz*, 18 BULL. AM. ACAD. PSYCHIATRY & L. 203, 210 (1990).

⁴¹⁶ *Id.*

⁴¹⁷ *Id.*

study further indicated that while judicial denial of a patient's request to refuse treatment decreased from 2.9 percent to 1.2 percent after *Rivers*, only 6 percent of the patients expressing a desire to stop treatment actually received a judicial hearing.⁴¹⁸ Consequently, while hospitals and physicians during the pre-*Rivers* era encouraged patients to inquire about the risks and implications of antipsychotic drug use, the study revealed that since the *Rivers* decision, health care workers have been less inclined to refute a patient's request to discontinue antipsychotic medication.⁴¹⁹ The study attributed this decrease to the time delay involved with formal competency hearings, and noted that on average, patients would not receive medication anywhere from one to three months prior to the initiation of the hearing.⁴²⁰

There is real harm that may result from the refusal of antipsychotic medication and the subsequent delay in the judicial process. For those patients awaiting a formal competency hearing, the Ciccone study found a regression in the mental health of some patients, many of whom ultimately required emergency medication, seclusion, and even physical restraint.⁴²¹ In the event the patient becomes physically violent, other patients and staff members are the most obvious victims.⁴²² Thus, the ironic aspect of the "rights driven approach" is that a patient exercising her right to refuse treatment may ultimately be physically restrained by staff members. Consequently, while respect for the patient's freedom of choice is critical, it is yet to be determined whether the perils of withholding treatment outweighs this right.

In addition to potentially violent consequences, the patient may experience permanent mental and/or physical damage as a result of the

⁴¹⁸*Id.* at 211.

⁴¹⁹*Id.*

⁴²⁰*Id.* at 212. Note that in 12 studies studying 5,000 cases of patient refusals, the court sustained only 3 percent of these refusals with a time delay of 48 days on average. Not one of the studies reported clinical benefit to the patient from a delay in treatment. Brakel & Davis, *supra* note 6, at 456. It is interesting to note that judges sustained only 3 percent of these treatment refusals. Researchers have concluded that judges have tended to still think like physicians (but without the training) when forced to make treatment decisions. Consequently, rights based cases like *Rogers* and *Rivers* have not cause the "collapse of the mental health profession" as some clinicians have feared; but the delays caused by these decisions have resulted in more harm than the legal community would like to admit. *Id.*

⁴²¹*Id.* at 213.

⁴²²WEINER & WETTSTEIN, *supra* note 394, at 120.

delay in treatment.⁴²³ Treatment delays incur institutional costs and harms as well. Hospitals must assume a custodial position for the patient, and the estimated cost of hospitalization over a four and one-half month period is \$50,000.00.⁴²⁴

Commentators from both the medical and legal communities believe that a "treatment-driven"⁴²⁵ approach may reduce the controversy surrounding a patient's "right to refuse" treatment, and simultaneously improve the quality of patient care in these situations.⁴²⁶ The treatment-driven approach suggests that a patient's right to refuse treatment should be determined prior to hospitalization and without a separate judicial hearing.⁴²⁷ Under this approach, the patient is protected because her rights are fully documented in a judicial hearing prior to hospitalization.⁴²⁸ Moreover, since competency is determined prior to hospitalization, treatment is facilitated and the conundrum of confinement can be avoided.⁴²⁹ Finally, the patient under the treatment-driven approach may assert her right to refuse medication after recovery, when she is competent.⁴³⁰

The treatment-driven approach has found legislative support in Utah, Michigan, Iowa, Kansas, Delaware, and South Carolina, where statutes expressly authorize this mode of decision making.⁴³¹ Skeptics, however, are concerned with whether the right to refuse treatment can be preserved once the patient has been hospitalized.⁴³² To counter this problem, patient treatment plans should be periodically reviewed by specially designated review teams and independent psychiatrists.⁴³³ In addition, the patient

⁴²³*Id.* at 457.

⁴²⁴*Id.* at 460.

⁴²⁵This model is also referred to as the "medical model" approach.

⁴²⁶Appelbaum & Gutheil, *The Right to Refuse Treatment: The Real Issue is Quality of Care*, 9 BULL. AM. ACAD. PSYCHIATRY & L. 199, 201 (1982).

⁴²⁷Appelbaum, *supra* note 409, at 416.

⁴²⁸Stone, *The Right to Refuse Treatment: Why Psychiatrists Should and Can Make it Work*, 38 ARCH. GEN. PSYCHIATRY 358, 362 (1981).

⁴²⁹*Id.* at 362.

⁴³⁰Brakel & Davis, *supra* note 6, at 450.

⁴³¹*Id.* at 470 (An example of such a statute can be found in UTAH CODE ANN. Sec. 62A-12-234(c) (1991)).

⁴³²Brakel & Davis, *supra* note 6, at 470.

⁴³³*Id.*

may request a formal review by the institution once every month or two, and there is always the opportunity for a judicial hearing.⁴³⁴

Independent clinical review is yet another approach used by several states. Under this approach, if the patient refuses treatment, the hospital conducts an independent clinical review to determine patient competency and the appropriateness of the patient's treatment plan.⁴³⁵ In *Rennie v. Klein*,⁴³⁶ the United States Court of Appeals for the Third Circuit upheld New Jersey's independent clinical review policy against a due process attack, when it determined the decision to administer antipsychotic drugs against a patient's will "must be based on accepted professional judgment and the procedures specified in New Jersey Administrative Bulletin 78-3 satisfied due process requirements."⁴³⁷

One problem with clinical review was identified in *Rogers*, where certain hospitalized patients might not receive treatment if they are determined to be competent.⁴³⁸ Therefore, the question arises as to what can be done with these patients who are hospitalized without the prospect of treatment.⁴³⁹

As the foregoing discussion illustrates, the right to refuse treatment is a controversial issue that plagues both medical and legal communities. Paradoxically, the patient who desires to discontinue treatment, may often find himself physically and involuntarily confined to a mental hospital for several months longer than anticipated. Furthermore, as many members of the medical community assert that the right to refuse treatment is not a solution to the underlying problem of inadequate patient care, maybe these individuals should concentrate their efforts to promote the patient's right to proper and effective treatment,⁴⁴⁰ especially since a disproportionately low number of patients actually refuse treatment.⁴⁴¹

⁴³⁴*Id.* at 471. The patient would receive treatment during the interim period. See Brakel and Davis, *supra* note 6, at 471.

⁴³⁵Brakel & Davei, *supra* note 6, at 471.

⁴³⁶720 F.2d 266 (3rd Cir. 1983).

⁴³⁷*Id.* at 268-69.

⁴³⁸*Rogers v. Okin*, 478 F.Supp. 1342 (D. Mass. 1979).

⁴³⁹Appelbaum, *supra* note 409, at 415.

⁴⁴⁰*Id.* at 201.

⁴⁴¹Appelbaum & Gutheil, *supra* note 426, at 200.

CONCLUSION

The ultimate goal of a careful risk-benefit analysis of TD is, obviously, improving patient care. Yet, the benefits of a consistent utilization of such an analysis will undoubtedly stretch much further. As tension within the medical community diminishes, the road will be paved for the development of concrete legal and judicial standards. As these fact-based principles emerge, societal tensions will be mitigated and most importantly, clinicians will have clear treatment paths which they can consistently implement and trust. Although we lack the answers to all the problems associated with TD, as consensus grows and cooperation is fostered, the medical, legal, and social consequences will inevitably be greatly minimized.

